UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

777 Old Saw Mill River Road Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 847-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of each of the registrant's classes of common stock as of July 22, 2019:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,848,970
Common Stock, $.001 par value	107,983,401

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
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"ARCALYST®", "EYLEA®", "Libtayo®" (in the United States), "Regeneron®", "Regeneron Genetics Center®", "Veloci-Bi™", "VelociGene®", "VelociMab®", "VelocImmune®", "VelociMouse®", "VelociSuite®", and "ZALTRAP®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In millions, except share data)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,045.5	$ 1,467.7
Marketable securities	1,624.2	1,342.2
Accounts receivable - trade, net	1,920.2	1,723.7
Accounts receivable from Sanofi	252.0	226.4
Accounts receivable from Bayer	283.7	293.1
Inventories	1,317.2	1,151.2
Prepaid expenses and other current assets	208.2	243.3
Total current assets	6,651.0	6,447.6
Marketable securities	2,884.6	1,755.0
Property, plant, and equipment, net	2,676.6	2,575.8
Deferred tax assets	821.6	828.7
Other noncurrent assets	139.8	127.4
Total assets	$ 13,173.6	$ 11,734.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 244.0	$ 218.2
Accrued expenses and other current liabilities	876.7	772.1
Deferred revenue from Sanofi	424.3	246.7
Deferred revenue - other	168.1	205.8
Total current liabilities	1,713.1	1,442.8
Finance lease liabilities	711.3	708.5
Deferred revenue from Sanofi	544.2	279.3
Deferred revenue - other	181.2	184.9
Other noncurrent liabilities	267.9	361.7
Total liabilities	3,417.7	2,977.2
Stockholders' equity:		
Preferred Stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,911,354 in 2019 and 2018	—	—
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 111,889,570 in 2019 and 111,084,951 in 2018	0.1	0.1
Additional paid-in capital	4,263.6	3,911.6
Retained earnings	5,918.2	5,254.3
Accumulated other comprehensive income (loss)	15.8	(12.3)
Treasury Stock, at cost; 4,018,269 shares in 2019 and 3,990,021 shares in 2018	(441.8)	(396.4)
Total stockholders' equity	9,755.9	8,757.3
Total liabilities and stockholders' equity	$ 13,173.6	$ 11,734.5

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(Unaudited)
(In millions, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Statements of Operations				
Revenues:				
Net product sales	$ 1,205.3	$ 996.4	$ 2,309.7	$ 1,984.3
Sanofi collaboration revenue	349.1	237.8	595.5	427.2
Bayer collaboration revenue	289.0	262.9	565.2	510.8
Other revenue	90.3	110.9	175.1	197.2
	1,933.7	1,608.0	3,645.5	3,119.5
Expenses:				
Research and development	1,048.3	529.3	1,690.1	1,027.9
Selling, general, and administrative	417.3	364.8	828.1	695.6
Cost of goods sold	67.0	36.0	137.9	105.2
Cost of collaboration and contract manufacturing	85.5	55.7	193.8	101.4
	1,618.1	985.8	2,849.9	1,930.1
Income from operations	315.6	622.2	795.6	1,189.4
Other income (expense):				
Other (expense) income, net	(82.9)	40.8	(9.1)	65.4
Interest expense	(8.0)	(6.9)	(15.7)	(13.3)
	(90.9)	33.9	(24.8)	52.1
Income before income taxes	224.7	656.1	770.8	1,241.5
Income tax expense	(31.6)	(104.7)	(116.6)	(212.1)
Net income	$ 193.1	$ 551.4	$ 654.2	$ 1,029.4
Net income per share - basic	$ 1.77	$ 5.12	$ 6.00	$ 9.56
Net income per share - diluted	$ 1.68	$ 4.82	$ 5.69	$ 8.97
Weighted average shares outstanding - basic	109.2	107.8	109.1	107.7
Weighted average shares outstanding - diluted	114.6	114.5	115.0	114.7
Statements of Comprehensive Income				
Net income	$ 193.1	$ 551.4	$ 654.2	$ 1,029.4
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on debt securities	14.4	3.4	30.5	(7.7)
Unrealized (loss) gain on cash flow hedges	(1.4)	0.6	(2.4)	2.0
Comprehensive income	$ 206.1	$ 555.4	$ 682.3	$ 1,023.7

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
(In millions)

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2018	1.9	—	111.1	$ 0.1	$ 3,911.6	$ 5,254.3	$ (12.3)	(4.0)	$ (396.4)	$ 8,757.3
Issuance of Common Stock in connection with exercise of stock options	—	—	0.6	—	140.9	—	—	—	—	140.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	—	—	(10.7)	—	—	—	—	(10.7)
Issuance/distribution of Common Stock in connection with Company 401(k) Savings Plan	—	—	—	—	4.3	—	—	0.1	6.2	10.5
Repurchases of Common Stock from Sanofi	—	—	—	—	—	—	—	(0.1)	(54.0)	(54.0)
Stock-based compensation charges	—	—	—	—	114.8	—	—	—	—	114.8
Adjustment upon adoption of new accounting standard	—	—	—	—	—	9.7	—	—	—	9.7
Net income	—	—	—	—	—	461.1	—	—	—	461.1
Other comprehensive gain, net of tax	—	—	—	—	—	—	15.1	—	—	15.1
Balance, March 31, 2019	1.9	—	111.7	0.1	4,160.9	5,725.1	2.8	(4.0)	(444.2)	9,444.7
Issuance of Common Stock in connection with exercise of stock options	—	—	0.3	—	13.9	—	—	—	—	13.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(0.1)	—	(29.7)	—	—	—	—	(29.7)
Issuance/distribution of Common Stock in connection with Company 401(k) Savings Plan	—	—	—	—	9.3	—	—	—	2.4	11.7
Stock-based compensation charges	—	—	—	—	109.2	—	—	—	—	109.2
Net income	—	—	—	—	—	193.1	—	—	—	193.1
Other comprehensive gain, net of tax	—	—	—	—	—	—	13.0	—	—	13.0
Balance, June 30, 2019	1.9	—	111.9	$ 0.1	$ 4,263.6	$ 5,918.2	$ 15.8	(4.0)	$ (441.8)	$ 9,755.9

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited) ***(continued)***

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2017	1.9	—	109.5	$ 0.1	$ 3,512.9	$ 2,946.7	$ 0.6	(3.8)	$ (316.2)	$ 6,144.1
Issuance of Common Stock in connection with exercise of stock options	—	—	0.1	—	13.6	—	—	—	—	13.6
Issuance of Common Stock in connection with Company 401(k) Savings Plan	—	—	0.1	—	(0.7)	—	—	—	—	(0.7)
Stock-based compensation charges	—	—	—	—	85.8	—	—	—	—	85.8
Cumulative-effect adjustment upon adoption of new accounting standards	—	—	—	—	—	(136.9)	(6.6)	—	—	(143.5)
Net income	—	—	—	—	—	478.0	—	—	—	478.0
Other comprehensive loss, net of tax	—	—	—	—	—	—	(9.7)	—	—	(9.7)
Balance, March 31, 2018	1.9	—	109.7	0.1	3,611.6	3,287.8	(15.7)	(3.8)	(316.2)	6,567.6
Issuance of Common Stock in connection with exercise of stock options	—	—	0.4	—	19.8	—	—	—	—	19.8
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(0.2)	—	(31.9)	—	—	—	—	(31.9)
Repurchases of Common Stock from Sanofi	—	—	—	—	—	—	—	(0.1)	(37.6)	(37.6)
Stock-based compensation charges	—	—	—	—	113.1	—	—	—	—	113.1
Net income	—	—	—	—	—	551.4	—	—	—	551.4
Other comprehensive gain, net of tax	—	—	—	—	—	—	4.1	—	—	4.1
Balance, June 30, 2018	1.9	—	109.9	$ 0.1	$ 3,712.6	$ 3,839.2	$ (11.6)	(3.9)	$ (353.8)	$ 7,186.5

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)
(In millions)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net income	$ 654.2	$ 1,029.4
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	103.1	70.0
Non-cash compensation expense	213.7	189.2
Other non-cash items, net	110.7	(54.9)
Deferred taxes	(125.3)	(15.5)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer, and trade accounts receivable	(256.8)	(64.9)
Increase in inventories	(168.2)	(182.1)
Decrease in prepaid expenses and other assets	42.5	59.4
Increase (decrease) in deferred revenue	401.1	(84.2)
Increase in accounts payable, accrued expenses, and other liabilities	110.3	67.0
Total adjustments	431.1	(16.0)
Net cash provided by operating activities	1,085.3	1,013.4
Cash flows from investing activities:		
Purchases of marketable and other securities	(2,189.1)	(1,181.2)
Sales or maturities of marketable securities	745.9	462.2
Capital expenditures	(168.9)	(191.4)
Net cash used in investing activities	(1,612.1)	(910.4)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	155.1	34.1
Payments in connection with Common Stock tendered for employee tax obligations	(40.5)	(31.9)
Repurchases of Common Stock	(10.0)	—
Net cash provided by financing activities	104.6	2.2
Net (decrease) increase in cash, cash equivalents, and restricted cash	(422.2)	105.2
Cash, cash equivalents, and restricted cash at beginning of period	1,480.2	825.2
Cash, cash equivalents, and restricted cash at end of period	$ 1,058.0	$ 930.4

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in millions, except per share data)

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron," "Company," "we," "us," and "our") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's condensed consolidated financial statements for such periods. The results of operations for any interim period are not necessarily indicative of the results for the full year. The December 31, 2018 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

We adopted Accounting Standards Codification ("ASC") 842, *Leases*, on January 1, 2019 (the "effective date") and used the effective date as our date of initial application. See Note 8. The new standard requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability for future lease payments and a right-of-use asset representing its right to use the underlying asset over the lease term. We elected the practical expedients upon transition, which permitted companies to not reassess lease identification, classification, and initial direct costs under the new standard for leases that commenced prior to the effective date. Upon adoption of the new standard, we recognized right-of-use assets of $33.2 million related to operating leases as of January 1, 2019. The impact of adopting the standard for the facilities that we had historically applied build-to-suit and capital lease accounting was not material to our Condensed Consolidated Financial Statements. Prior period amounts have not been adjusted in connection with the adoption of this standard.

2. Product Sales

Net product sales consist of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
Net Product Sales in the United States	**2019**	**2018**	**2019**	**2018**
EYLEA®	$ 1,160.3	$ 992.0	$ 2,234.4	$ 1,976.0
Libtayo®	40.8	—	67.6	—
ARCALYST®	4.2	4.4	7.7	8.3
	$ 1,205.3	$ 996.4	$ 2,309.7	$ 1,984.3

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the three and six months ended June 30, 2019 and 2018. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	56%	56%	57%	55%
McKesson Corporation	34%	35%	32%	37%

The following table summarizes the provisions, and credits/payments, for sales-related deductions during the six months ended June 30, 2019 and 2018.

(Unless otherwise noted, dollars in millions, except per share data)

	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2018	$ 41.1	$ 42.0	$ 8.3	$ 91.4
Provisions	185.1	114.0	33.3	332.4
Credits/payments	(139.5)	(87.9)	(30.9)	(258.3)
Balance as of June 30, 2019	$ 86.7	$ 68.1	$ 10.7	$ 165.5
Balance as of December 31, 2017	$ 29.9	$ 34.1	$ 21.3	$ 85.3
Provisions	97.7	102.1	19.9	219.7
Credits/payments	(91.1)	(98.5)	(24.4)	(214.0)
Balance as of June 30, 2018	$ 36.5	$ 37.7	$ 16.8	$ 91.0

3. Collaboration Agreements

a. Sanofi

The collaboration revenue we earned from Sanofi is detailed below:

	Three Months Ended June 30,		Six Months Ended June 30,	
Sanofi Collaboration Revenue	**2019**	**2018**	**2019**	**2018**
Antibody:				
Reimbursement of Regeneron research and development expenses	$ 81.8	$ 64.5	$ 156.3	$ 124.9
Reimbursement of Regeneron commercialization-related expenses	121.1	103.7	237.7	189.1
Regeneron's share of profits (losses) in connection with commercialization of antibodies	38.8	(68.8)	11.0	(143.7)
Other	36.5	31.7	49.4	49.0
Total Antibody	278.2	131.1	454.4	219.3
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses	36.5	77.0	82.9	150.9
Reimbursement of Regeneron commercialization-related expenses	1.7	2.1	4.0	3.2
Other	32.7	27.6	54.2	53.8
Total Immuno-oncology	70.9	106.7	141.1	207.9
	$ 349.1	$ 237.8	$ 595.5	$ 427.2

(Unless otherwise noted, dollars in millions, except per share data)

Antibody

The Company is party to a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). Under the companies' Antibody License and Collaboration Agreement, following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. All other agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi. The Company recognized as research and development expense $10.3 million and $9.9 million during the three months ended June 30, 2019 and 2018, respectively, and during the six months ended June 30, 2019 and 2018, the Company recognized as research and development expense $19.6 million and $23.8 million, respectively, its share of antibody development expenses that Sanofi incurred related to Dupixent® (dupilumab), Praluent® (alirocumab), and Kevzara® (sarilumab).

Effective January 7, 2018, the Company and Sanofi entered into a letter agreement (the "Letter Agreement") in connection with, among other matters, the allocation of additional funds to certain activities relating to dupilumab and REGN3500 (collectively, the "Dupilumab/REGN3500 Eligible Investments"). Refer to the "*Immuno-Oncology*" section below for further details regarding the Letter Agreement. During the first quarter of 2019, Sanofi elected to sell, and we elected to purchase (in cash), 24,143 shares of the Company's Common Stock in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments. Consequently, we recorded the cost of the shares received, or $10.0 million, as Treasury Stock during the first quarter of 2019.

Sanofi leads commercialization activities for products developed under the Antibody Collaboration, subject to the Company's right to co-promote such products. In addition to profit and loss sharing, the Company is entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling twelve-month basis. The amount of variable consideration related to our share of profits and losses, as well as sales milestones, is deemed to be constrained as of June 30, 2019, and therefore has not been included in the transaction price.

The following table summarizes contract balances in connection with the Company's Antibody Collaboration with Sanofi:

	June 30, 2019	December 31, 2018
Accounts receivable	$ 248.8	$ 138.2
Deferred revenue	$ 339.4	$ 236.1

Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2019
Increase due to shipments of commercial supplies to Sanofi	$ 172.8
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (75.1)

As we recognize Sanofi antibody collaboration revenue in an amount equal to the amount we have the right to invoice and such amount corresponds directly with the value to Sanofi of our performance to date, we do not disclose the value of the transaction price allocated to our remaining unsatisfied performance obligations.

Immuno-Oncology

In 2015, the Company and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The IO Collaboration is governed by an Amended and Restated Immuno-oncology Discovery and Development Agreement ("Amended IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement").

Effective December 31, 2018, the Company and Sanofi entered into an Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company ("IO Development Activities") under the 2015 IO Discovery Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 (the "BCMAxCD3

(Unless otherwise noted, dollars in millions, except per share data)

Program") and (ii) MUC16 and CD3 (the "MUC16xCD3 Program") through clinical proof-of-concept. The Amended IO Discovery Agreement provided for Sanofi's payment of $461.9 million to the Company as consideration for (x) the termination of the 2015 IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the 2015 IO Discovery Agreement during the fourth quarter of 2018.

If Sanofi exercises its option to license rights to a BCMAxCD3 Program antibody or MUC16xCD3 Program antibody thereunder, it will co-develop these drug candidates with the Company through product approval. Sanofi will fund development costs up front for a BCMAxCD3 Program antibody and we will reimburse half of the total development costs for such antibody from our share of future IO Collaboration profits to the extent they are sufficient for this purpose. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for a MUC16xCD3 Program antibody.

Under the terms of the IO License and Collaboration Agreement, the parties are co-developing Libtayo (cemiplimab), an antibody targeting the receptor known as programmed cell death protein 1 (PD-1). The parties share equally, on an ongoing basis, agreed-upon development expenses for Libtayo. Pursuant to the Letter Agreement, the Libtayo development budget was increased and the Company has agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to the Libtayo development and Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares (of which 1,042,732 currently remains available) of our Common Stock directly or indirectly owned by Sanofi through September 30, 2020. If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. During the first quarter of 2019, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 106,972 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded the cost of the shares received, or $44.0 million as Treasury Stock during the first quarter of 2019. Refer to the "*Antibody*" section above for a description of share transactions related to Dupilumab/REGN3500 Eligible Investments.

The Company has principal control over the development of Libtayo and leads commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States and the parties equally share profits and losses from worldwide sales. As it relates to the IO Collaboration, "Reimbursement of Regeneron commercialization-related expenses" in the table above represents reimbursement of costs by Sanofi in connection with the commercialization of Libtayo outside of the United States.

The following table summarizes contract balances in connection with the Company's IO Collaboration with Sanofi:

	June 30, 2019	December 31, 2018
Accounts (payable) receivable	$ (0.8)	$ 77.9
Deferred revenue	$ 629.1	$ 289.9

Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2019
Increase as a result of payment received from Sanofi	$ 415.9
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (55.3)
Revenue recognized that was added to deferred revenue during the period	$ (25.0)

(Unless otherwise noted, dollars in millions, except per share data)

The aggregate amount of the transaction price under the IO Collaboration allocated to the Company's performance obligation that was unsatisfied (or partially unsatisfied) as of June 30, 2019 was $1,251.1 million. This amount is expected to be recognized as revenue over the remaining period in which the Company is obligated to satisfy its performance obligation in connection with performing development activities.

b. Bayer

Revenue earned in connection with our Bayer EYLEA collaboration is as follows (note that the table excludes amounts in connection with our Bayer Ang2 antibody and PDGFR-beta antibody collaboration agreements, which were previously terminated):

	Three Months Ended June 30,		Six Months Ended June 30,	
Bayer EYLEA Collaboration Revenue	**2019**	**2018**	**2019**	**2018**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 269.0	$ 246.3	$ 518.3	$ 478.4
Reimbursement of Regeneron EYLEA development expenses	8.0	3.7	10.6	7.1
Other	12.0	12.7	36.3	24.6
	$ 289.0	$ 262.7	$ 565.2	$ 510.1

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA outside the United States. Bayer markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, the Company is entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net product sales. In addition, the Company and Bayer share the funding of agreed-upon EYLEA development costs.

c. Teva

In September 2016, the Company and Teva entered into a collaboration agreement (the "Teva Collaboration Agreement") to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with Mitsubishi Tanabe Pharma Corporation. In connection with the Teva Collaboration Agreement, Teva made a $250.0 million non-refundable up-front payment in September 2016. The Company leads global development activities, and the parties share development costs equally, on an ongoing basis, under a global development plan. The Company is also responsible for the manufacture and supply of fasinumab globally.

The Company recognized $61.1 million and $68.8 million of revenue for the three months ended June 30, 2019 and 2018, respectively, and $114.8 million and $127.4 million for the six months ended June 30, 2019 and 2018, respectively, in connection with the Teva Collaboration Agreement.

The following table summarizes contract balances in connection with the Teva Collaboration Agreement:

	June 30, 2019	December 31, 2018
Accounts receivable (recorded within Prepaid expenses and other current assets)	$ 36.7	$ 28.8
Deferred revenue	$ 149.1	$ 194.5

Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2019
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (45.9)

The aggregate amount of the transaction price under the Teva Collaboration Agreement allocated to the Company's performance obligation that was unsatisfied (or partially unsatisfied) as of June 30, 2019 was $357.7 million. This amount is expected to be recognized as revenue over the remaining period in which the Company is obligated to satisfy its performance obligation in connection with performing development activities.

d. Alnylam

In April 2019, the Company and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference (RNAi) therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. The collaboration is governed by a Master Collaboration Agreement (the "Master Agreement") (including the form of a License Agreement and a Co-Commercialization Collaboration Agreement). Under the terms of the Master Agreement, we made an up-front payment of $400.0 million to Alnylam, which was recorded in Research and development expense during the second quarter of 2019. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200.0 million in clinical proof-of-principle milestones for eye or CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Commercialization Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more INDs (or their equivalent in certain other countries) for programs in the eye and CNS.

In connection with the collaboration, we and Alnylam also entered into a Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, we purchased shares of Alnylam common stock for aggregate cash consideration of $400.0 million.

4. Net Income Per Share

The Company's basic net income per share amounts have been computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Net income - basic and diluted	$ 193.1	$ 551.4	$ 654.2	$ 1,029.4
(Shares in millions)				
Weighted average shares - basic	109.2	107.8	109.1	107.7
Effect of dilutive securities:				
Stock options	5.4	6.7	5.9	7.0
Weighted average shares - diluted	114.6	114.5	115.0	114.7
Net income per share - basic	$ 1.77	$ 5.12	$ 6.00	$ 9.56
Net income per share - diluted	$ 1.68	$ 4.82	$ 5.69	$ 8.97

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive include the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
(Shares in millions)	**2019**	**2018**	**2019**	**2018**
Stock options	18.3	14.9	18.1	14.9
Restricted stock	0.4	0.1	—	0.1

5. Marketable Securities

Marketable securities as of June 30, 2019 and December 31, 2018 consist of both available-for-sale debt securities of investment grade issuers (see below and Note 6) as well as equity securities of publicly traded companies (see Note 6).

The following tables summarize the Company's investments in available-for-sale debt securities:

	Amortized	Unrealized		Fair
As of June 30, 2019	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 3,774.2	$ 22.1	$ (1.7)	$ 3,794.6
U.S. government and government agency obligations	119.4	0.2	(0.2)	119.4
Sovereign bonds	26.8	0.5	—	27.3
Commercial paper	99.6	0.1	—	99.7
Certificates of deposit	53.7	0.1	—	53.8
	$ 4,073.7	$ 23.0	$ (1.9)	$ 4,094.8
As of December 31, 2018				
Corporate bonds	$ 2,734.8	$ 1.0	$ (17.4)	$ 2,718.4
U.S. government and government agency obligations	110.4	—	(1.0)	109.4
Sovereign bonds	7.6	—	—	7.6
Commercial paper	113.8	—	—	113.8
Certificates of deposit	60.0	—	—	60.0
	$ 3,026.6	$ 1.0	$ (18.4)	$ 3,009.2

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of June 30, 2019 mature at various dates through June 2024. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	June 30, 2019	December 31, 2018
Maturities within one year	$ 1,624.2	$ 1,342.2
Maturities after one year through five years	2,470.6	1,667.0
	$ 4,094.8	$ 3,009.2

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The following table shows the fair value of the Company's available-for-sale debt securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
As of June 30, 2019	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 312.8	$ (0.2)	$ 564.7	$ (1.5)	$ 877.5	$ (1.7)
U.S. government and government agency obligations	—	—	76.4	(0.2)	76.4	(0.2)
	$ 312.8	$ (0.2)	$ 641.1	$ (1.7)	$ 953.9	$ (1.9)
As of December 31, 2018						
Corporate bonds	$ 1,482.6	$ (6.1)	$ 801.6	$ (11.3)	$ 2,284.2	$ (17.4)
U.S. government and government agency obligations	—	—	99.1	(1.0)	99.1	(1.0)
	$ 1,482.6	$ (6.1)	$ 900.7	$ (12.3)	$ 2,383.3	$ (18.4)

There were no realized losses on sales of marketable securities, and realized gains were not material, for the three and six months ended June 30, 2019 and 2018.

With respect to marketable securities, for the three and six months ended June 30, 2019 and 2018, amounts reclassified from Accumulated other comprehensive (loss) income into Other income (expense), net were related to realized gains on sales of debt securities.

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6. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis consist of the following:

		Fair Value Measurements at Reporting Date Using	
As of June 30, 2019	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**
Available-for-sale debt securities:			
Corporate bonds	$ 3,794.6	—	$ 3,794.6
U.S. government and government agency obligations	119.4	—	119.4
Sovereign bonds	27.3	—	27.3
Commercial paper	99.7	—	99.7
Certificates of deposit	53.8	—	53.8
Equity securities (unrestricted)	67.0	$ 67.0	—
Equity securities (restricted)	347.0	62.2	284.8
	$ 4,508.8	$ 129.2	$ 4,379.6
As of December 31, 2018			
Available-for-sale debt securities:			
Corporate bonds	$ 2,718.4	—	$ 2,718.4
U.S. government and government agency obligations	109.4	—	109.4
Sovereign bonds	7.6	—	7.6
Commercial paper	113.8	—	113.8
Certificates of deposit	60.0	—	60.0
Equity securities (unrestricted)	43.6	$ 43.6	—
Equity securities (restricted)	44.4	—	44.4
	$ 3,097.2	$ 43.6	$ 3,053.6

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities.

The Company held certain restricted equity securities as of June 30, 2019, including its investment in Alnylam (see Note 3), which are subject to transfer restrictions until 2023.

During the three and six months ended June 30, 2019, we recorded $116.9 million and $74.1 million, respectively, of net unrealized losses on equity securities in Other income (expense), net. During the three and six months ended June 30, 2018, we recorded $16.5 million and $25.9 million, respectively, of net unrealized gains on equity securities in Other income (expense), net.

As of June 30, 2019 and December 31, 2018, the Company had $45.5 million in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets.

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7. Inventories

Inventories consist of the following:

	June 30, 2019	December 31, 2018
Raw materials	$ 229.7	$ 226.8
Work-in-process	663.1	571.1
Finished goods	34.1	24.4
Deferred costs	390.3	328.9
	$ 1,317.2	$ 1,151.2

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

8. Leases

We conduct certain of our research, development, and administrative activities at leased facilities. We also lease certain warehouses and vehicles. As described in Note 1, during the first quarter of 2019, we adopted ASC 842, *Leases*.

We determine if an arrangement is a lease considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Our lease terms may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. We account for lease components (e.g., rental payments) separately from non-lease components (e.g., common area maintenance costs).

Right-of-use assets and lease liabilities are recognized at lease commencement date based on the present value of lease payments over the lease term, unless there is a transfer of title or purchase option we are reasonably certain to exercise. For leases where an implicit rate is not readily determinable, we use our incremental borrowing rate based on information available at the lease commencement date to determine the present value of future lease payments. Lease expense for operating leases is recognized on a straight-line basis over the expected lease term.

Operating leases

Amounts recognized in our Condensed Consolidated Balance Sheets and Statements of Operations included in this report associated with operating leases were not material. Operating lease right-of-use assets are included within Other noncurrent assets, and lease liabilities are included in Accrued expenses and other current liabilities and Other noncurrent liabilities.

Finance leases

In March 2017, we entered into a Participation Agreement with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively, the "Participants"). In March 2017, we also entered into a Lease and Remedies Agreement with BAL, pursuant to which we have leased laboratory and office facilities in Tarrytown, New York (the "Facility") for a five-year term. The Participation Agreement, the Lease and Remedies Agreement, and certain other related agreements were amended and restated in May 2019, among other things, to revise certain covenants, representations and warranties, and events of default to be substantially similar to those set forth in the agreement governing the Company's revolving credit facility (as so amended and restated, the "Participation Agreement" and the "Lease," respectively). The Lease requires us to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month LIBOR, plus an applicable margin that varies with our debt rating and total leverage ratio. The Participation Agreement and the Lease include an option for us to elect to extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. We also have the option prior to the end of the term of the Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Participation Agreement, all accrued and unpaid interest and yield thereon, and all other outstanding amounts under the Participation Agreement, the Lease, and certain related documents or (b) sell the Facility to a third

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party on behalf of BAL. The advances under the Participation Agreement mature, and all amounts outstanding thereunder will become due and payable in full, at the end of the term of the Lease.

Prior to January 1, 2019, for certain of the premises under the Lease we were deemed, in substance, to be the owner of the buildings (collectively, the "Build-to-Suit Buildings"). Upon the adoption of ASC 842, the classification of the Build-to-Suit Buildings, for which the construction period had been completed, was reassessed and, consequently, they were derecognized and recognized as a finance lease. These premises, along with the other premises under the Lease, are classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised.

The agreements governing the Lease financing contain financial and operating covenants, which are substantially similar to the covenants set forth in the Company's revolving credit facility. The Company was in compliance with all such covenants as of June 30, 2019.

Amounts recognized in the Condensed Consolidated Balance Sheet related to the Lease are included in the table below. Other than the Lease described above, we had no leases accounted for as finance leases as of June 30, 2019.

	Classification	June 30, 2019
Finance lease assets	Property, plant, and equipment, net [(a)]	$ 667.3
Finance lease liabilities	Finance lease liabilities (noncurrent)	$ 711.3

[(a)] Finance lease assets are recorded net of accumulated amortization of $68.9 million as of June 30, 2019.

As of December 31, 2018, property, plant, and equipment, at cost, included $723.9 million of leased property under the Lease. Accumulated amortization related to these assets amounted to $61.7 million as of December 31, 2018.

Finance lease costs consist of the following:

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Amortization of right-of-use assets	$ 3.7	$ 7.2
Interest on lease liabilities	7.3	14.5
	$ 11.0	$ 21.7

Other information related to our finance lease includes the following:

	June 30, 2019
Remaining lease term (in years)	2.67
Discount rate	3.14%

(Unless otherwise noted, dollars in millions, except per share data)

Supplemental information

The following is an analysis of lease liability maturities as of June 30, 2019:

	Operating Leases	Finance Leases
2019	$ 4.0	$ 12.0
2020	8.2	22.1
2021	5.8	21.8
2022	3.0	725.4
2023	2.6	—
2024	2.9	—
Thereafter	4.2	—
Total undiscounted lease payments	30.7	781.3
Imputed interest	(3.0)	(63.3)
Debt financing costs	—	(6.7)
Total lease liabilities	$ 27.7	$ 711.3

As of December 31, 2018, the estimated future minimum noncancelable lease commitments, excluding the purchase price we would be obligated to pay if we were to exercise our option to purchase the Facility, were as follows:

	Operating Leases	Capital and Facility Lease Obligations
2019	$ 10.4	$ 26.4
2020	3.8	28.4
2021	3.4	27.9
2022	2.2	7.0
2023	1.5	—
Thereafter	4.1	—
	$ 25.4	$ 89.7

9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 14.1% and 16.0% for the three months ended June 30, 2019 and 2018, respectively, and 15.1% and 17.1% for the six months ended June 30, 2019 and 2018, respectively. The Company's effective tax rate for the three and six months ended June 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, stock-based compensation, federal tax credits for research activities, and, to a lesser extent, the foreign-derived intangible income deduction, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee.

The Company's effective tax rate for the three and six months ended June 30, 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, the foreign-derived intangible income deduction, and federal tax credits for research activities.

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10. Statement of Cash Flows

As described in Note 6, included in our purchases of marketable securities during the six months ended June 30, 2019 is our purchase of Alnylam common stock.

The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheet to the total of the same such amounts shown in the Condensed Consolidated Statement of Cash Flows:

	June 30, 2019	June 30, 2018
Cash and cash equivalents	$ 1,045.5	$ 917.9
Restricted cash included in Other noncurrent assets	12.5	12.5
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$ 1,058.0	$ 930.4

Restricted cash consists of amounts held by financial institutions pursuant to contractual arrangements.

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable, accrued expenses, and other liabilities as of June 30, 2019 and December 31, 2018 were $74.7 million and $54.5 million, respectively, of accrued capital expenditures. Included in accounts payable, accrued expenses, and other liabilities as of June 30, 2018 and December 31, 2017 were $38.4 million and $41.8 million, respectively, of accrued capital expenditures.

As described in Note 3, during the six months ended June 30, 2019, we purchased (by issuing a credit towards the amount owed by Sanofi) 106,972 shares of our Common Stock from Sanofi to satisfy Sanofi's funding obligation related to Libtayo development costs, and recorded the cost of the shares received, or $44.0 million, as Treasury Stock. During the six months ended June 30, 2018, we purchased (by issuing a credit towards the amount owed by Sanofi) 121,601 shares of our Common Stock from Sanofi, and recorded the cost of the shares received, or $37.6 million, as Treasury Stock.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Unless otherwise noted below, the Company is unable to predict the outcome, or estimate a range of possible loss or possible gain, of the respective proceedings. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted.

Proceedings Relating to '287 Patent and '163 Patent

The Company is a party to patent infringement litigation initiated by the Company involving its European Patent No. 1,360,287 (the "'287 Patent") and its European Patent No. 2,264,163 (the "'163 Patent"). Each of these patents concerns genetically engineered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings, the Company claims infringement of several claims of the '287 Patent and the '163 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '163 Patent (as applicable).

On September 25, 2013, the Company commenced patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting the '287 Patent and '163 Patent. Following a trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent, the court issued a final judgment on February 1, 2016, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. On appeal,

the Court of Appeal (Civil Division of England and Wales) reversed the English High Court's decision and held that the '287 Patent and '163 Patent are both valid and infringed by Kymab and subsequently issued a final order, which enjoins Kymab from infringing the '287 Patent and '163 Patent (subject to certain exceptions) and requires Kymab to destroy or deliver to a third party all products and antibodies and cells engineered to produce antibodies which infringe the '287 Patent and '163 Patent (subject to certain exceptions). Thereafter, the Supreme Court of the United Kingdom granted Kymab's application for permission to appeal the order made by the Court of Appeal with respect to an issue of validity of the '287 Patent and the '163 Patent and scheduled an oral hearing for February 11–12, 2020. The provisions of the final order of the Court of Appeal are stayed pending final determination of Kymab's appeal to the Supreme Court of the United Kingdom. The Company has also been awarded a portion of the legal fees incurred by it in connection with the proceedings in the English High Court and the Court of Appeal described above. On July 31, 2019, the Company filed an action in the English High Court for a calculation of damages relating to Kymab's infringement of the '287 Patent and the '163 Patent.

On July 8 and July 13, 2016, notices of opposition against the '163 Patent were filed in the European Patent Office (the "EPO") by Merus N.V. and Kymab and Novo Nordisk A/S, respectively. The notices assert, as applicable, lack of novelty, lack of inventive step, and insufficiency. Following an oral hearing before the Opposition Division of the EPO on February 5–7, 2018, the Opposition Division upheld the '163 Patent without amendments. Kymab, Merus, and Novo Nordisk each filed a notice of appeal of the Opposition Division's decision on February 9, 2018, May 25, 2018, and June 26, 2018, respectively. On January 7, 2019, Merus withdrew its appeal of the '163 Patent in the EPO in connection with the previously announced global settlement.

Proceedings Relating to Praluent (alirocumab) Injection

As described in greater detail below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. against the Company and Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent, which the Company is jointly developing and commercializing with Sanofi.

In the United States, Amgen has asserted U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and seeks a permanent injunction to prevent the Company and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, "Commercializing") Praluent. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. The first jury trial in this litigation (the "First Trial") was held in the United States District Court for the District of Delaware (the "District Court") from March 8 to March 16, 2016. During the course of the First Trial, the District Court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of the Company and the Sanofi defendants that there was no willful infringement of the asserted patent claims by the Company or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen in the First Trial, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On October 5, 2017, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") reversed in part the District Court's decision and remanded for a new trial on the issues of written description and enablement. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious.

On January 3, 2019, the District Court held oral argument in the remanded proceedings on the Company and the Sanofi defendants' motion for judgment on the pleadings regarding Amgen's willful infringement claim. On January 18, 2019, the District Court entered an order (i) denying the Company and the Sanofi defendants' motion for summary judgment on validity, (ii) denying Amgen's motion for partial summary judgment on estoppel, and (iii) granting the Company and the Sanofi defendants' cross-motion for summary judgment on estoppel. On February 8, 2019, the District Court granted the Company and the Sanofi defendants' motion for judgment on the pleadings, thereby dismissing Amgen's claim of willful infringement. The second jury trial in this litigation (the "Second Trial") was held before the District Court in February 2019 to determine the validity of Amgen's asserted patent claims. On February 25, 2019, the jury returned a verdict in the Second Trial generally in favor of Amgen, finding that two claims of the '165 Patent and one claim of the '741 Patent were not invalid. The jury also found that two claims of the '165 Patent were invalid for lack of adequate written description while rejecting the lack of enablement challenges to those two claims. On February 25, 2019, the District Court notified the parties that a remedies trial, if necessary, would be held following the resolution of any appeals from the jury verdict in the Second Trial on the validity of Amgen's asserted patents. The District Court's final judgment is expected to be issued following resolution of the parties' post-trial motions (including Amgen's motion for a permanent injunction discussed below). The Company and the Sanofi defendants plan to appeal any aspect of the final judgment that is adverse to the Company and the Sanofi defendants.

On March 18, 2019, Amgen filed a motion for a permanent injunction to prohibit the Company and the Sanofi defendants from Commercializing Praluent in the United States (a "Permanent Injunction"), and an oral hearing on this motion was held in June

2019. Previously, the Federal Circuit stayed and then vacated a Permanent Injunction granted by the District Court in connection with the First Trial.

On July 25, 2016, Amgen filed a lawsuit against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of Amgen's European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, by Praluent. The lawsuit also seeks a permanent injunction, damages, an accounting of profits, and costs and interest. On February 8, 2017, the court temporarily stayed this litigation on terms mutually agreed by the parties.

Also on July 25, 2016, Amgen filed a lawsuit for infringement of the '124 Patent against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf, Germany (the "Düsseldorf Regional Court"), seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages. On November 14, 2017, the Düsseldorf Regional Court issued a decision staying the infringement proceedings until a decision of the Opposition Division of the EPO concerning the pending opposition filed by the Company, Sanofi, and several other opponents against the '124 Patent (as discussed below). Following Amgen's request to reopen the proceedings in light of the issuance of the Preliminary Opinion (as defined below), the Düsseldorf Regional Court held an oral hearing on September 11, 2018 and ruled on December 10, 2018 that the infringement proceedings would be reopened. On July 11, 2019, the Düsseldorf Regional Court found that Praluent infringes the '124 Patent and granted an injunction prohibiting the Company and Sanofi's manufacture, sale, and marketing of Praluent in Germany (the "July 11 Decision"). On July 12, 2019, the Company and Sanofi appealed the July 11 Decision to the Higher Regional Court of Düsseldorf (the "Higher Regional Court"). An oral hearing on the merits of the appeal to the Higher Regional Court has been scheduled for April 2, 2020. On August 5, 2019, the Higher Regional Court denied the Company and Sanofi's request for a provisional stay of the July 11 Decision pending the appeal on the merits.

On July 12, 2018, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie S.A. filed an action in the Federal Patents Court (the "FPC") in Munich, Germany, seeking a compulsory license from Amgen based on the '124 Patent for the continued commercializing of Praluent in Germany. This compulsory license action included a request for a provisional compulsory license. The FPC held an oral hearing on September 6, 2018 and denied Sanofi's request for the provisional compulsory license. On January 16, 2019, the Sanofi parties appealed the FPC's denial of the provisional compulsory license to the Federal Court of Justice (the "FCJ") of Germany. The FCJ held an oral hearing on June 4, 2019 on the appeal of the provisional compulsory license ruling and dismissed Sanofi's appeal. The compulsory license action remains pending.

On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi Chimie (subsequently added as a defendant). Amgen is seeking the prohibition of allegedly infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time. On April 10, 2017, the Company and the Sanofi parties filed briefs seeking invalidation of certain of the claims of the '124 Patent, and Amgen filed a response on July 28, 2017. Oral hearing on this infringement lawsuit (originally scheduled for February 12, 2019) has yet to be scheduled.

The '124 Patent is also subject to opposition proceedings in the EPO seeking to invalidate certain of its claims, which were initiated by Sanofi on February 24, 2016 and, separately, by the Company, Sanofi, and several other opponents on November 24, 2016. On December 13, 2017, the Opposition Division of the EPO issued a preliminary, non-binding opinion (the "Preliminary Opinion") regarding the validity of the '124 Patent, indicating that it currently considers the claims of a new request filed by Amgen in response to the opposition to satisfy the requirements for patentability. An oral hearing on the oppositions against the '124 Patent was held on November 28–30, 2018, at which the Opposition Division upheld the validity of the '124 Patent's claims in amended form. The Company and Sanofi filed notices of appeal to the Technical Board of Appeal of the EPO on November 30, 2018.

The Company has recorded an accrual for loss contingencies associated with the '124 Patent proceedings discussed above. The ultimate resolution of these proceedings is not expected to have a material impact on the Company’s financial statements.

On May 19, 2017, Amgen filed a lawsuit for infringement of Amgen's Japanese Patent Nos. 5,906,333 (the "'333 Patent") and 5,705,288 (the "'288 Patent") in the Tokyo District Court Civil Division (the "Tokyo District Court") against Sanofi K.K. Amgen's complaint alleges that manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) infringe the '333 and '288 Patents. The complaint further seeks a permanent injunction, disposal of product, and court costs. The Company has not been named as a defendant in this litigation. On January 17, 2019, the Tokyo District Court upheld the validity of the '333 Patent and '288 Patent and ordered a permanent injunction against Sanofi K.K. to stop manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) and to dispose of all product. However, the Tokyo District Court stayed the enforcement of such injunction pending appeal to the Intellectual Property High Court of Japan (the "IPHC"). On January 30, 2019, Sanofi K.K. appealed the Tokyo District Court's decision in the infringement proceedings to the IPHC, and an oral hearing has been scheduled for October 30, 2019.

Proceedings Relating to Dupixent (dupilumab) Injection

On March 20, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation filed a lawsuit against Amgen and Immunex Corporation, a wholly owned subsidiary of Amgen, in the United States District Court for the District of Massachusetts seeking a declaratory judgment that the Company's and the other plaintiffs' Commercializing of Dupixent does not directly or indirectly infringe U.S. Patent No. 8,679,487 (the "'487 Patent") owned by Immunex Corporation relating to antibodies that bind the human interleukin-4 receptor. On May 1, 2017, the Company and the other plaintiffs filed a notice of voluntary dismissal of this action without prejudice.

On March 23, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation initiated an *inter partes* review ("IPR") in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of the '487 Patent. On July 28 and 31, 2017, the same parties filed two additional IPR petitions in the USPTO seeking declarations of invalidity of the '487 Patent based on different grounds (the "Additional IPR Petitions"). On October 4, 2017, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a decision on the first IPR petition and declined to institute an IPR proceeding to review the validity of the '487 Patent. On February 15, 2018, the PTAB issued two decisions instituting the Company's and Sanofi's Additional IPR Petitions on all claims of the '487 Patent for which review had been requested. Oral hearings on the Additional IPR Petitions before the PTAB were held on November 14, 2018. On February 14, 2019, the PTAB issued final written decisions on the Additional IPR Petitions, invalidating all 17 claims of the '487 Patent as obvious based on one of the Additional IPR Petitions while declining to hold the challenged claims of the '487 Patent invalid based on the other. In April 2019, the parties filed notices of appeal with the Federal Circuit appealing the PTAB's respective adverse final written decisions on the Additional IPR Petitions.

On April 5, 2017, Immunex Corporation filed a lawsuit against the Company, Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation, and Aventisub LLC in the United States District Court for the Central District of California seeking a judgment of patent infringement of the '487 Patent and a declaratory judgment of infringement of the '487 Patent, in each case by the Company's and the other defendants' Commercializing of Dupixent; monetary damages (together with interest); an order of willful infringement of the '487 Patent, which would allow the court in its discretion to award damages up to three times the amount assessed; costs and expenses of the lawsuit; and attorneys' fees. Immunex is not seeking an injunction in this proceeding at this time. On June 21, 2017, the court denied a motion to dismiss Immunex's complaint previously filed by the Company and the Sanofi parties. On June 28, 2017, the Company and the Sanofi parties filed an answer to Immunex's complaint and counterclaims against Immunex and Amgen (which was amended on October 31, 2017 to, among other things, add an inequitable conduct allegation), and Immunex and Amgen filed an answer to the counterclaims on July 28, 2017. A combined hearing on the construction of certain disputed claim terms of the '487 Patent and the Company and the Sanofi parties' motion for summary judgment on the issue of indefiniteness of the '487 Patent claims was held on July 12, 2018. On August 24, 2018, the court issued an order denying this motion and construed the disputed claim terms as proposed by Amgen. On February 28, 2019, the court granted a joint stipulation by the parties to stay the litigation pending resolution of the appeals of the PTAB's final written decisions on the Additional IPR Petitions discussed above.

On September 30, 2016, Sanofi initiated a revocation proceeding in the United Kingdom to invalidate the U.K. counterpart of European Patent No. 2,292,665 (the "'665 Patent"), another patent owned by Immunex relating to antibodies that bind the human interleukin-4 receptor. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the currently pending EPO opposition proceedings initiated by the Company and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions occurred on November 20, 2017, at which the claims of the '665 Patent were found invalid and the patent was revoked. A final written decision of revocation of the '665 Patent was issued by the EPO on January 4, 2018. Immunex filed a notice of appeal of the EPO's

decision on January 31, 2018. On September 20, 2017 and September 21, 2017, respectively, the Company and Sanofi initiated opposition proceedings in the EPO against Immunex's European Patent No. 2,990,420 (the "'420 Patent"), a divisional patent of the '665 Patent (*i.e.*, a patent that shares the same priority date, disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). The oral hearing before the EPO on the oppositions occurred on February 14–15, 2019, at which the '420 Patent was revoked in its entirety. Immunex filed a notice of appeal of the EPO's decision on May 31, 2019. The original patent term of the Immunex patents is set to expire in 2021.

Proceedings Relating to EYLEA (aflibercept) Injection and ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion

On March 19, 2018, Novartis Vaccines and Diagnostics, Inc., Novartis Pharma AG, and Grifols Worldwide Operations Limited (collectively, the "Novartis Parties") filed a lawsuit against the Company in the United States District Court for the Southern District of New York, seeking a judgment of patent infringement of U.S. Patent No. 5,688,688 (the "'688 Patent") by the Company's manufacture of aflibercept (the active ingredient used in both EYLEA and ZALTRAP); monetary damages (together with interest) for a limited period prior to the '688 Patent expiration; an order of willful infringement of the '688 Patent (dismissed on October 24, 2018); costs and expenses of the lawsuit; and attorneys' fees. The '688 Patent expired on November 18, 2014. The Novartis Parties are not seeking an injunction in these proceedings. On March 20, 2019, the court issued its Opinion and Order on Claim Construction (the "Claim Construction Order") in the '688 Patent infringement litigation. Pursuant to the Claim Construction Order, on April 1, 2019, the court approved a joint stipulation and entered a partial judgment of noninfringement of the '688 Patent of nine asserted claims. As a result, only one claim for infringement of the '688 Patent remains pending.

On May 14, 2019, the Company filed an IPR in the USPTO seeking a declaration of invalidity of the '688 Patent.

Department of Justice Investigation

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST, and ZALTRAP); and certain other related documents and communications. The Company is cooperating with this investigation.

12. Recently Issued Accounting Standards

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded instead of reducing the amortized cost of the investment. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We do not expect the adoption of this standard to have a significant impact on our financial statements or internal controls; however, the ultimate impact will depend on the composition of the Company's portfolio of financial instruments as of the adoption date.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Libtayo® (cemiplimab) Injection, fasinumab, and evinacumab; the likelihood and timing of achieving any of our anticipated clinical development milestones referenced in this report; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory

approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation EYLEA, Dupixent, Praluent, Kevzara, Libtayo, fasinumab, and evinacumab; the extent to which the results from the research and development programs conducted by us or our collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; the ability of our collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to our products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation and other related proceedings relating to EYLEA, Dupixent, and Praluent described further in Note 11 to our Condensed Consolidated Financial Statements included in this report, the ultimate outcome of any such proceedings, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. Our commercialized medicines and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases, and rare diseases.

Selected financial information is summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues	$ 1,933.7	$ 1,608.0	$ 3,645.5	$ 3,119.5
Net income	$ 193.1	$ 551.4	$ 654.2	$ 1,029.4
Net income per share - diluted	$ 1.68	$ 4.82	$ 5.69	$ 8.97

We currently have seven products that have received marketing approval:

Product	Disease Area[1]	Territory			
		U.S.	EU	Japan	ROW[6]
EYLEA (aflibercept) Injection[2]	- Neovascular age-related macular degeneration (wet AMD)	a	a	a	a
	- Diabetic macular edema (DME)	a	a	a	a
	- Macular edema following retinal vein occlusion (RVO), which includes macular edema following central retinal vein occlusion (CRVO) and macular edema following branch retinal vein occlusion (BRVO)	a	a	a	a
	- Myopic choroidal neovascularization (mCNV)		a	a	a
	- Diabetic retinopathy	a			
Dupixent (dupilumab) Injection[3]	- Atopic dermatitis (in adults)	a	a	a	a
	- Atopic dermatitis (in adolescents)	a	a		
	- Asthma (in adults and adolescents)	a	a	a	a
	- Chronic rhinosinusitis with nasal polyposis (CRSwNP)	a			
Praluent (alirocumab) Injection[3]	- LDL-lowering in heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) (in adults)	a	a	a	a
	- Cardiovascular risk reduction in patients with established cardiovascular disease	a	a		
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	- Rheumatoid arthritis (RA) (in adults)	a	a	a	a
Libtayo (cemiplimab) Injection[3][4]	- Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	a	a		a
ARCALYST® (rilonacept) Injection for Subcutaneous Use	- Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	a			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[5]	- Metastatic colorectal cancer (mCRC)	a	a	a	a

[1] Refer to label information in each territory for specific indication

[2] In collaboration with Bayer (outside the United States)

[3] In collaboration with Sanofi

[4] Marketed as Libtayo (cemiplimab-rwlc) Injection in the United States

[5] Pursuant to a 2015 amended and restated ZALTRAP agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP, and Sanofi pays us a percentage of aggregate net sales of ZALTRAP

[6] Rest of world. Checkmark in this column indicates that the product has received marketing approval in at least one country outside of the United States, European Union (EU), or Japan

Marketed Products

Net Product Sales of Regeneron-Discovered Products[1]	**Three Months Ended June 30,**					
(In millions)	**2019**			**2018**		
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**
EYLEA[1]	$ 1,160.3	$ 715.3	$ 1,875.6	$ 992.0	$ 665.9	$ 1,657.9
Libtayo	40.8	—	40.8	—	—	—
ARCALYST	4.2	—	4.2	4.4	—	4.4
Net product sales recorded by Regeneron	$ 1,205.3			$ 996.4		
Net product sales recorded by Sanofi[1]:						
Dupixent	$ 454.7	$ 102.6	$ 557.3	$ 180.9	$ 28.3	$ 209.2
Praluent	$ 26.5	$ 47.2	$ 73.7	$ 41.4	$ 32.1	$ 73.5
Kevzara	$ 34.2	$ 24.3	$ 58.5	$ 18.8	$ 5.3	$ 24.1
ZALTRAP	$ 1.3	$ 25.3	$ 26.6	$ 2.7	$ 25.7	$ 28.4

	Six Months Ended June 30,					
	2019			**2018**		
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**
EYLEA[1]	$ 2,234.4	$ 1,384.7	$ 3,619.1	$ 1,976.0	$ 1,289.9	$ 3,265.9
Libtayo	67.6	—	67.6	—	—	—
ARCALYST	7.7	—	7.7	8.3	—	8.3
Net product sales recorded by Regeneron	$ 2,309.7			$ 1,984.3		
Net product sales recorded by Sanofi[1]:						
Dupixent	$ 757.7	$ 173.3	$ 931.0	$ 298.1	$ 42.5	$ 340.6
Praluent	$ 49.4	$ 88.2	$ 137.6	$ 73.2	$ 60.2	$ 133.4
Kevzara	$ 54.9	$ 37.3	$ 92.2	$ 28.2	$ 8.3	$ 36.5
ZALTRAP	$ 1.8	$ 49.3	$ 51.1	$ 5.1	$ 49.6	$ 54.7

[1] Bayer records net product sales of EYLEA outside the United States and Sanofi records global net product sales of Dupixent, Praluent, Kevzara, and ZALTRAP. Refer to "Overview" above and "Collaboration Agreements" below for further details.

Programs in Clinical Development

All 21 of our product candidates in clinical development, including the five U.S. Food and Drug Administration (FDA) approved products which we are investigating in additional indications, were discovered in our research laboratories and are summarized below. We used our *VelocImmune*® technology to generate each of the antibodies in the table below. There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, and changes in the competitive landscape affecting a product candidate. Refer to Part II, Item 1A. "Risk Factors" for a description of these and other risks and uncertainties that may affect our clinical programs.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
EYLEA			- Non-proliferative diabetic retinopathy (NPDR) in patients without DME	- Pre-filled syringe (U.S.)
Dupixent (dupilumab)[a] *Antibody to IL-4R alpha subunit*		- Grass allergy - Peanut allergy	- Atopic dermatitis in adolescents and pediatrics (6–11 years of age)[d] - Atopic dermatitis in pediatrics (6 months–5 years of age) (Phase 2/3)[d] - Asthma in pediatrics (6–11 years of age) - Eosinophilic esophagitis (EOE) (Phase 2/3)[c] - Chronic obstructive pulmonary disease (COPD)	- Auto-injector for 300 mg dose (U.S. and EU) - CRSwNP (EU and Japan)
Praluent (alirocumab)[a] *Antibody to PCSK9*			- Homozygous familial hypercholesterolemia (HoFH)[c] in adults and pediatrics - HeFH in pediatrics	
Kevzara (sarilumab)[a] *Antibody to IL-6R*		- Polyarticular-course juvenile idiopathic arthritis (pcJIA) - Systemic juvenile idiopathic arthritis (sJIA)	- Polymyalgia rheumatica - Giant cell arteritis	
Libtayo (cemiplimab)[a] *Antibody to PD-1[h]*	- Solid tumors and advanced hematologic malignancies	- Metastatic or locally advanced CSCC[d] - Basal cell carcinoma (BCC) (potentially pivotal study)	- First-line non-small cell lung cancer (NSCLC) - Second-line cervical cancer - Adjuvant CSCC	
Fasinumab[b][f] (REGN475) *Antibody to NGF*			- Osteoarthritis pain of the knee or hip[e]	
Evinacumab[f] (REGN1500) *Antibody to ANGPTL3*		- Refractory hypercholesterolemia (both HeFH and non-FH) - Severe hypertriglyceridemia	- HoFH[c][d]	
REGN1979 *Bispecific antibody targeting CD20 and CD3*	- Certain B-cell malignancies[c]	- Relapsed/refractory follicular lymphoma (FL)		
Garetosmab[f] (REGN2477) *Antibody to Activin A*		- Fibrodysplasia ossificans progressiva (FOP)[c][e] (potentially pivotal study)		

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
REGN3500[a] *Antibody to IL-33. Studied as monotherapy and in combination with Dupixent.*		- Asthma - COPD - Atopic dermatitis		
REGN1908-1909[f] *Multi-antibody therapy to Feld1*		- Cat allergy		
REGN-EB3[g] **(REGN3470-3471-3479)** *Multi-antibody therapy to Ebola virus*			- Ebola virus infection (Phase 2/3)[c][j]	
Pozelimab[f] **(REGN3918)** *Antibody to C5*		- Paroxysmal nocturnal hemoglobinuria (PNH)		
REGN5069 *Antibody to GFRα3*		- Osteoarthritis pain of the knee		
REGN3048-3051[g] *Multi-antibody therapy to Middle East Respiratory Syndrome (MERS) virus*	- MERS virus infection			
REGN3767[f] *Antibody to LAG-3*	- Solid tumors and advanced hematologic malignancies			
REGN4461 *Agonist antibody to leptin receptor (LEPR)*	- Lipodystrophy and obesity			
REGN4018[a] *Bispecific antibody targeting MUC16 and CD3*	- Platinum-resistant ovarian cancer			
REGN4659[f] *Antibody to CTLA4*	- Advanced NSCLC			
REGN5458[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma			
REGN5713-5714-5715 *Antibody to Betv1*	- Birch allergy			

[a] In collaboration with Sanofi

[b] In collaboration with Teva and Mitsubishi Tanabe Pharma

[c] FDA granted orphan drug designation

[d] FDA granted Breakthrough Therapy designation

[e] FDA granted Fast Track designation

[f] Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate.

[g] Sanofi did not opt-in to the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate. We and the Biomedical Advanced Research Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) are parties to agreements whereby HHS provides certain funding to support research, development, and manufacturing of these antibodies.

[h] Studied as monotherapy and in combination with other antibodies and treatments

[i] Regulatory application submitted. Information in this column relates to U.S., EU, and Japan submissions only.

[j] Included in randomized controlled trial run by World Health Organization

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to be an integrated, multi-product biotechnology company that provides patients and medical professionals with important options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*® technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human antibody technology (*VelocImmune*) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

General

Developing and commercializing new medicines entails significant risk and expense. Before significant revenues from the commercialization of our antibody candidates or new indications for our marketed products can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of EYLEA, Dupixent, Praluent, Kevzara, and Libtayo. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products; the scope and progress of our research and development efforts; the timing of certain expenses; the continuation of our collaborations, in particular with Sanofi and Bayer, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators; and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2019 to date were, and select milestones for the next twelve months are, as follows:

Clinical Program	2019 Events to Date	Select 2019–2020 Milestones (next 12 months)
EYLEA	- Approved by FDA for the treatment of diabetic retinopathy - Resubmitted sBLA for pre-filled syringe	- FDA decision on sBLA for pre-filled syringe (target action date of August 12, 2019) - Initiate a study of a high-dose formulation of aflibercept - Initiate Phase 3 program in retinopathy of prematurity (ROP)
Dupixent (dupilumab; IL-4R Antibody)	- Approved by FDA for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) - Approved by European Commission (EC) for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) - Reported that the Phase 3 study in pediatric patients (6–11 years of age) with severe atopic dermatitis met its primary and secondary endpoints - Approved by EC for treatment of asthma in adults and adolescents - Submitted regulatory applications in EU and Japan for CRSwNP - Approved by FDA for CRSwNP - Initiated Phase 3 study in COPD - EC approved MAA for 200 mg auto-injector presentation - FDA issued Complete Response Letter (CRL) regarding the sBLA for 200 mg auto-injector - Submitted sBLA and MAA for 300 mg auto-injector - Completed Phase 2a trial in grass allergy	- Submit sBLA and Marketing Authorization Application (MAA) for expanded atopic dermatitis indication in pediatric patients (6–11 years of age) - EU and Japan decisions on applications for CRSwNP - FDA decision on application for 300 mg auto-injector (target action date of March 20, 2020) - Present results from Phase 2a trial in grass allergy at medical meeting
Praluent (alirocumab; PCSK9 Antibody)	- Approved by EC for a new indication to reduce cardiovascular risk in adults with established ASCVD - Approved by FDA for a new indication to reduce the risk of heart attack, stroke and unstable angina requiring hospitalization in adults with established CV disease - Approved by FDA for the treatment of adults with primary hyperlipidemia (including HeFH) to reduce low-density lipoprotein cholesterol (LDL-C)	- Report results from Phase 3 study in HoFH
Libtayo (cemiplimab; PD-1 Antibody)	- Conditionally approved by EC for treatment of advanced CSCC - Initiated Phase 3 adjuvant study in CSCC	- Continue patient enrollment in NSCLC and various other studies - Initiate Phase 2 neoadjuvant study in CSCC - Report results from Phase 2 study in BCC

Clinical Program *(continued)*	2019 Events to Date	Select 2019–2020 Milestones (next 12 months)
Fasinumab (NGF Antibody)	- Completed patient enrollment in Phase 3 efficacy studies and Phase 3 long-term safety study in osteoarthritis pain	
Evinacumab (ANGPTL3 Antibody)		- Report results from Phase 3 study in HoFH
REGN1979 (CD20 and CD3 Antibody)	- Reported updated data from Phase 1 study in patients with relapsed or refractory B-cell non-Hodgkin lymphoma - Began recruiting patients in Phase 2 study in relapsed/refractory FL	- Initiate potentially pivotal Phase 2 program in aggressive non-Hodgkin lymphoma
Garetosmab (Activin A Antibody)		- Report results from Phase 2 study in FOP
REGN3500 (IL-33 Antibody)	- Reported that the Phase 2 study in asthma met its primary and key secondary endpoints	- Initiate Phase 2b study in asthma - Report results from Phase 2 study in COPD
REGN1908-1909 (Feld1 Antibody)	- Initiated Phase 2 study in cat allergic asthmatics	- Report results from Phase 2 study in cat allergic asthmatics
REGN-EB3 (Multi-antibody therapy to Ebola virus)	- Included in randomized controlled trial run by World Health Organization	
Pozelimab (C5 Antibody)	- Initiated Phase 2 study in PNH	
REGN5069 (GFRα3 Antibody)	- Initiated Phase 2 study in osteoarthritis pain	
REGN3048-3051 (Multiple-antibody therapy to MERS)		- Complete Phase 1 study in healthy volunteers
REGN4461 (LEPR Agonist Antibody)		- Initiate Phase 2 study in generalized lipodystrophy
REGN5458 (BCMA and CD3 Antibody)	- Initiated Phase 1 study in multiple myeloma	- Report interim results from Phase 1 study in multiple myeloma
REGN5713-5714-5715 (Betv1 Antibody)	- Initiated Phase 1 study in birch allergy	

Collaboration Agreements

Collaborations with Sanofi

Antibody. We are collaborating with Sanofi on the global development and commercialization of various antibodies and antibody product candidates (Dupixent, Praluent, Kevzara, and REGN3500) (the Antibody Collaboration). Under the terms of the Antibody License and Collaboration Agreement (LCA), following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. All other agreed-upon development costs incurred by both companies are funded 100% by Sanofi. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose.

Effective January 7, 2018, we and Sanofi entered into a letter agreement (Letter Agreement) amending the LCA in connection with, among other matters, the allocation of additional funds to certain proposed activities relating to dupilumab and REGN3500 (collectively, the Dupilumab/REGN3500 Eligible Investments). Pursuant to the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to the Dupilumab/REGN3500 Eligible Investments for the quarterly periods commencing on January 1, 2018 and ending on September 30, 2020 by selling up to an aggregate of 600,000 shares (of which 565,091 currently remains available) of our Common Stock directly or indirectly owned by Sanofi. Refer to the *"Immuno-Oncology"* section below for further details regarding the Letter Agreement.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-promote such products on a country-by-country basis. We have exercised our option to co-promote Dupixent, Praluent, and Kevzara in the United States. We have thus far not exercised any of our options to co-promote these antibodies outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi equally share profits and losses from sales within the

United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit and loss sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales of antibodies (subject to this agreement) outside the United States exceed $1.0 billion on a rolling twelve-month basis.

Immuno-Oncology. In 2015, we and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Amended and Restated Immuno-oncology Discovery and Development Agreement (Amended IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the execution of the original Immuno-oncology Discovery and Development Agreement in 2015 (2015 IO Discovery Agreement), which has been replaced by the Amended IO Discovery Agreement (as discussed below), Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the 2015 IO Discovery Agreement, we were to spend up to $1,090.0 million (IO Discovery Budget) to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept, and Sanofi was to reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits. The original term of the 2015 IO Discovery Agreement was to continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget was exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs.

Effective December 31, 2018, the Company and Sanofi entered into the Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company (IO Development Activities) under the 2015 IO Discovery Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 (the BCMAxCD3 Program) and (ii) MUC16 and CD3 (the MUC16xCD3 Program) through clinical proof-of-concept. The Amended IO Discovery Agreement provided for Sanofi's payment of $461.9 million to the Company as consideration for (x) the termination of the 2015 IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the 2015 IO Discovery Agreement during the fourth quarter of 2018.

Under the terms of the Amended IO Discovery Agreement, the Company is required to conduct development activities with respect to (i) the BCMAxCD3 Program through the earlier of clinical proof-of-concept or the expenditure of $70.0 million (the BCMAxCD3 Program Costs Cap) and (ii) the MUC16xCD3 Program through the earlier of clinical proof-of-concept or the expenditure of $50.0 million (the MUC16xCD3 Program Costs Cap); provided that under certain circumstances, Sanofi will have the option to increase the MUC16xCD3 Program Costs Cap to $70.0 million by making a payment to the Company in the amount of $20.0 million.

Pursuant to the Amended IO Discovery Agreement, we are primarily responsible for conducting the IO Development Activities, other than certain clinical trials that may be funded separately by Sanofi, including antibody development, preclinical activities, toxicology studies, manufacture of clinical supplies, filing of Investigational New Drug Applications (INDs), and clinical development through proof-of-concept. We are obligated to reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized IO Collaboration products to the extent they are sufficient for this purpose. As the scope of the IO Development Activities has been limited, the exclusivity obligations of the parties under the Amended IO Discovery Agreement have been narrowed.

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when clinical proof-of-concept is established, the applicable Program Costs Cap is reached, or in certain other limited circumstances, Sanofi will have the option to license rights to the product candidate and other antibodies targeting the same targets for, with regard to BCMAxCD3, immuno-oncology indications, and with regard to MUC16xCD3, all indications, pursuant to the IO License and Collaboration Agreement, as amended. If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will receive a royalty on sales. Pursuant to the Amended IO Discovery Agreement, the parties agreed that (i) if Sanofi exercises its option with respect to a BCMAxCD3 Program antibody, Sanofi will lead the development and global commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) we will lead the development of such MUC16xCD3 Program antibody and commercialization of such MUC16xCD3 Program antibody within the United States and (y) Sanofi will lead the commercialization of such MUC16xCD3 Program antibody outside of the United States.

The Amended IO Discovery Agreement provides that Regeneron retains exclusive rights to all other immuno-oncology programs that were part of the 2015 IO Discovery Agreement, provided that Sanofi will receive a royalty on global sales of two product candidates currently in clinical development, REGN3767 and REGN4659. The Amended IO Discovery Agreement will terminate as of the earlier of (a) Sanofi having elected to exercise or not exercise its options with respect to the BCMAxCD3 Program and the MUC16xCD3 Program in accordance with the terms of the Amended IO Discovery Agreement and (b) December 31, 2022.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us in 2015. If Sanofi exercises its option to license rights to a BCMAxCD3 Program antibody or MUC16xCD3 Program antibody thereunder, it will co-develop these drug candidates with us through product approval under the terms of the IO License and Collaboration Agreement. Sanofi will fund development costs up front for a BCMAxCD3 Program antibody and we will reimburse half of the total development costs for such antibody from our share of future IO Collaboration profits to the extent they are sufficient for this purpose. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for a MUC16xCD3 Program antibody. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that immuno-oncology drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties are also co-developing Libtayo (cemiplimab), an antibody targeting PD-1. We have principal control over the development of Libtayo, and the parties share equally, on an ongoing basis, agreed-upon development expenses for Libtayo. Under the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligation with respect to Libtayo development costs for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to an aggregate of 800,000 shares (of which 477,641 currently remains available) of our Common Stock directly or indirectly owned by Sanofi.

If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or, as noted above, Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions.

With regard to Libtayo, we lead commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States and the parties equally share profits from worldwide sales. Sanofi has exercised its option to co-promote Libtayo in the United States. We will be entitled to a milestone payment of $375.0 million in the event that global sales of certain licensed products targeting PD-1 (including Libtayo), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with any of such licensed products targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

Collaboration with Bayer

EYLEA outside the United States. Since 2006, we and Bayer have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer collaborate on, and share the costs of, the development of EYLEA. Bayer markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits (including payments to us based on sales in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer at a faster rate. As a result, a portion of our share of EYLEA profits outside the United States will continue to be used to reimburse Bayer for this repayment obligation.

Within the United States, we retain exclusive commercialization rights to EYLEA and are entitled to all profits from such sales.

Collaboration with Teva

Fasinumab. In 2016, we entered into a collaboration agreement with Teva to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC). In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment in 2016. We lead global development activities, and the parties will share equally, on an ongoing basis, development costs under a global development plan. As of June 30, 2019, we had earned an aggregate of $120.0 million of development milestones from Teva and we are entitled to receive up to an aggregate of $340.0 million in additional development milestones and up to an aggregate of $1,890.0 million in contingent payments upon achievement of specified annual net sales amounts. We are responsible for the manufacture and supply of fasinumab globally.

Within the United States, we will lead commercialization activities, and the parties will share equally in any profits or losses in connection with commercialization of fasinumab. In the territory outside of the United States, Teva will lead commercialization activities and we will supply product to Teva at a tiered purchase price, which is calculated as a percentage of net sales of the product (subject to adjustment in certain circumstances).

Collaboration with Alnylam

In April 2019, we and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference (RNAi) therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system (CNS), in addition to a select number of targets expressed in the liver. The collaboration is governed by a Master Collaboration Agreement (the Master Agreement) (including the form of a License Agreement and a Co-Commercialization Collaboration Agreement). Under the terms of the Master Agreement, we made an up-front payment of $400.0 million to Alnylam. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200.0 million in clinical proof-of-principle milestones for eye or CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Commercialization Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the Research Term). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more INDs (or their equivalent in certain other countries) for programs in the eye and CNS.

At the stage of designation of a lead candidate for CNS programs and liver programs, the parties have alternating rights to be a lead party for collaboration products. At the stage of designation of a lead candidate for eye programs, we have the sole right to take the product forward as a licensee. The lead party is required to take the program forward under the License Agreement structure unless the other party exercises its rights to opt-in to a Co-Commercialization Collaboration Agreement, in which case the lead party is required to take the program forward under the Co-Commercialization Collaboration Agreement structure. Alnylam does not have rights to opt-in to a Co-Commercialization Collaboration Agreement for eye programs.

Under a License Agreement, the lead party is designated as the licensee and has the right to develop and commercialize the collaboration product under such program. The licensee will be responsible for its own costs and expenses incurred in connection with the development and commercialization of the collaboration products under the License Agreement. The licensee will pay to the licensor certain development and/or commercialization milestone payments totaling up to $150.0 million for each collaboration product. In addition, following the first commercial sale of the applicable collaboration product under a License Agreement, the licensee is required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the licensor based on the aggregate annual net sales of the collaboration product, subject to customary reductions.

For CNS programs and liver programs, as soon as a party is designated as a lead party, the other company has rights to opt-in to a Co-Commercialization Collaboration Agreement as a participating party. Under a Co-Commercialization Collaboration Agreement, the party designated as the lead party has operational responsibility and final decision-making authority on development and commercialization of the program and the parties will split profits and share costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions. If a party exercises its co-funding opt-out right, following the first commercial sale of the applicable collaboration product under a Co-Commercialization Collaboration Agreement, the lead party will be required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the other party based on the aggregate annual net sales of the collaboration product and the timing of the exercise of the co-funding opt-out right, subject to customary reductions. If the non-lead party does not initially opt-in to a Co-Commercialization Collaboration Agreement, the lead party has the right to take the program forward under a License Agreement structure.

Under the collaboration, when we are the licensee under a License Agreement or the lead party under a Co-Commercialization Collaboration Agreement, Alnylam will be responsible for the manufacture and supply of the product to us for Phase 1 and Phase 2 clinical trials.

In connection with the collaboration, we and Alnylam also entered into a Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, we purchased 4,444,445 shares of Alnylam common stock for aggregate cash consideration of $400.0 million.

The parties plan to negotiate and enter into a Co-Commercialization Collaboration Agreement for a silencing RNA (siRNA) therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic and a fully human monoclonal antibody targeting C5 being developed by us, with us as the licensee. The C5 siRNA Co-Commercialization Collaboration Agreement would generally be consistent with the financial terms in the form of the existing Co-Commercialization Collaboration Agreement with Alnylam. The C5 siRNA License Agreement would contain a flat low double-digit royalty on net sales of the combination product only subject to customary reductions, and there could be up to $325.0 million in commercial milestones.

Corporate Information

We were incorporated in the State of New York in 1988 and publicly listed in 1991. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number at that address is (914) 847-7000.

We make available free of charge on or through our Internet website (*http://www.regeneron.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Investors and other interested parties should note that we use our media and investor relations website (*http://newsroom.regeneron.com*) and our social media channels to publish important information about Regeneron, including information that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our media and investor relations website and the social media channels listed on our media and investor relations website, in addition to our SEC filings, press releases, conference calls, and webcasts.

The information contained on our websites and social media channels is not included as a part of, or incorporated by reference into, this report.

Results of Operations

Three and Six Months Ended June 30, 2019 and 2018

Net Income

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues	$ 1,933.7	$ 1,608.0	$ 3,645.5	$ 3,119.5
Operating expenses	(1,618.1)	(985.8)	(2,849.9)	(1,930.1)
Other income (expense), net	(90.9)	33.9	(24.8)	52.1
Income before income taxes	224.7	656.1	770.8	1,241.5
Income tax expense	(31.6)	(104.7)	(116.6)	(212.1)
Net income	$ 193.1	$ 551.4	$ 654.2	$ 1,029.4
Net income per share - diluted	$ 1.68	$ 4.82	$ 5.69	$ 8.97

Revenues

	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
(In millions)	**2019**	**2018**	**(Decrease)**	**2019**	**2018**	**(Decrease)**
Net product sales in the United States:						
EYLEA	$ 1,160.3	$ 992.0	$ 168.3	$ 2,234.4	$ 1,976.0	$ 258.4
Libtayo	40.8	—	40.8	67.6	—	67.6
ARCALYST	4.2	4.4	(0.2)	7.7	8.3	(0.6)
Sanofi and Bayer collaboration revenue:						
Sanofi	349.1	237.8	111.3	595.5	427.2	168.3
Bayer	289.0	262.9	26.1	565.2	510.8	54.4
Other revenue	90.3	110.9	(20.6)	175.1	197.2	(22.1)
Total revenues	$ 1,933.7	$ 1,608.0	$ 325.7	$ 3,645.5	$ 3,119.5	$ 526.0

Net Product Sales

Net product sales of EYLEA in the United States increased for the three and six months ended June 30, 2019, compared to the same periods in 2018, due to higher sales volume, partly offset by an increase in sales-related deductions primarily due to higher rebates and discounts. There were no sales of Libtayo for the three and six months ended June 30, 2018 as the FDA approved Libtayo for the treatment of patients with metastatic or locally advanced CSCC on September 28, 2018.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	**Rebates, Chargebacks, and Discounts**	**Distribution-Related Fees**	**Other Sales-Related Deductions**	**Total**
Balance as of December 31, 2018	$ 41.1	$ 42.0	$ 8.3	$ 91.4
Provisions	78.6	52.8	16.1	147.5
Credits/payments	(60.8)	(47.9)	(0.4)	(109.1)
Balance as of March 31, 2019	58.9	46.9	24.0	129.8
Provisions	106.5	61.2	17.2	184.9
Credits/payments	(78.7)	(40.0)	(30.5)	(149.2)
Balance as of June 30, 2019	$ 86.7	$ 68.1	$ 10.7	$ 165.5
Balance as of December 31, 2017	$ 29.9	$ 34.1	$ 21.3	$ 85.3
Provisions	48.5	51.7	11.2	111.4
Credits/payments	(30.7)	(42.0)	(14.7)	(87.4)
Balance as of March 31, 2018	47.7	43.8	17.8	109.3
Provisions	49.2	50.4	8.7	108.3
Credits/payments	(60.4)	(56.5)	(9.7)	(126.6)
Balance as of June 30, 2018	$ 36.5	$ 37.7	$ 16.8	$ 91.0

Sanofi Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2019**	**2018**	**2019**	**2018**
Antibody:				
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	$ 81.8	$ 64.5	$ 156.3	$ 124.9
Reimbursement of Regeneron commercialization-related expenses	121.1	103.7	237.7	189.1
Regeneron's share of profits (losses) in connection with commercialization of antibodies	38.8	(68.8)	11.0	(143.7)
Other	36.5	31.7	49.4	49.0
Total Antibody	278.2	131.1	454.4	219.3
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses - Discovery Agreement	11.1	38.3	24.9	73.6
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	25.4	38.7	58.0	77.3
Reimbursement of Regeneron commercialization-related expenses	1.7	2.1	4.0	3.2
Other	32.7	27.6	54.2	53.8
Total Immuno-oncology	70.9	106.7	141.1	207.9
Total Sanofi collaboration revenue	$ 349.1	$ 237.8	$ 595.5	$ 427.2

Antibody

Reimbursement of Regeneron antibody commercialization-related expenses represents reimbursement of internal and external costs incurred by Regeneron in connection with commercializing Praluent, Kevzara, and Dupixent.

During the three and six months ended June 30, 2019 and 2018, we and Sanofi shared commercial expenses related to Dupixent, Praluent, and Kevzara in accordance with the companies' Antibody License and Collaboration Agreement. As such, during the same periods in which we recorded reimbursements from Sanofi related to our commercialization expenses, we also recorded our share of combined profits/losses in connection with the companies commercializing Dupixent, Praluent, and Kevzara within Sanofi collaboration revenue. During the three and six months ended June 30, 2019, Sanofi collaboration revenues in connection with commercialization of antibodies were primarily impacted, compared to the same periods in 2018, by our share of higher net product sales of Dupixent, partly offset by an increase in the collaborations' Dupixent commercialization expenses. See "Marketed Products" section above for a summary of global net product sales recorded by Sanofi in connection with our Antibody License and Collaboration Agreement. Sanofi provides us with an estimate of our share of the profits or losses from commercialization of antibodies for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profits or losses is adjusted accordingly, as necessary.

In the second quarter of 2019, a portion of our share of profits in connection with commercialization of antibodies was used to reimburse Sanofi for a portion of development expenses that had been previously funded by Sanofi; such amount was not material for the three months ended June 30, 2019. We are only required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs.

Other Sanofi antibody revenue in the table above primarily relates to reimbursement for the manufacturing of commercial supplies.

Immuno-Oncology

Sanofi's reimbursement of immuno-oncology research and development costs under our IO Discovery Agreement decreased in the second quarter and first half of 2019, compared to the same periods in 2018, due to the impact of the Amended IO Discovery Agreement (see "Collaboration Agreements - Collaborations with Sanofi" above). Reimbursement of Regeneron immuno-oncology commercialization-related expenses represents reimbursement of internal and external costs incurred by Regeneron in connection

with commercializing Libtayo outside the United States. Other Sanofi immuno-oncology revenue primarily includes recognition of deferred revenue from up-front payments received in connection with the execution of the IO Collaboration agreements and the Amended IO Discovery Agreement, partly offset by our share of losses in connection with Sanofi's commercialization of Libtayo outside the United States.

Bayer Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2019**	**2018**	**2019**	**2018**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 269.0	$ 246.3	$ 518.3	$ 478.4
Reimbursement of Regeneron development expenses	8.0	3.9	10.6	7.8
Other	12.0	12.7	36.3	24.6
Total Bayer collaboration revenue	$ 289.0	$ 262.9	$ 565.2	$ 510.8

Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2019**	**2018**	**2019**	**2018**
Net product sales outside the United States	$ 715.3	$ 665.9	$ 1,384.7	$ 1,289.9
Regeneron's share of collaboration profit from sales outside the United States	$ 282.9	$ 259.4	$ 546.3	$ 504.5
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(13.9)	(13.1)	(28.0)	(26.1)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 269.0	$ 246.3	$ 518.3	$ 478.4

Bayer records revenue from sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profit, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Other Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2019**	**2018**	**2019**	**2018**
Teva collaboration revenue:				
Reimbursement of Regeneron research and development expenses	$ 36.5	$ 34.3	$ 68.7	$ 73.4
Other	24.6	34.5	46.1	54.0
Total Teva collaboration revenue	61.1	68.8	114.8	127.4
Other revenue	29.2	42.1	60.3	69.8
Total other revenue	$ 90.3	$ 110.9	$ 175.1	$ 197.2

In addition to Teva collaboration revenue (which is earned in connection with the development of fasinumab), "Total other revenue" in the table above includes, but is not limited to:

- Recognition of a portion of deferred revenue from up-front and other payments received from MTPC in connection with our fasinumab collaboration.

- Sanofi's reimbursement for manufacturing commercial supplies of ZALTRAP and a percentage of aggregate net sales of ZALTRAP under the terms of the Amended ZALTRAP Agreement.
- Royalties in connection with a June 2009 agreement with Novartis, under which we receive royalties on worldwide sales of Novartis' Ilaris® (canakinumab). The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion, and we are entitled to royalties until Novartis ceases sale of products subject to royalty.
- Recognition of revenue in connection with our agreements with BARDA related to REGN-EB3 for the treatment of Ebola virus infection.

Expenses

	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
(In millions, except headcount data)	**2019**	**2018**	**(Decrease)**	**2019**	**2018**	**(Decrease)**
Research and development	$ 1,048.3	$ 529.3	$ 519.0	$ 1,690.1	$ 1,027.9	$ 662.2
Selling, general, and administrative	417.3	364.8	52.5	828.1	695.6	132.5
Cost of goods sold	67.0	36.0	31.0	137.9	105.2	32.7
Cost of collaboration and contract manufacturing	85.5	55.7	29.8	193.8	101.4	92.4
Total operating expenses	$ 1,618.1	$ 985.8	$ 632.3	$ 2,849.9	$ 1,930.1	$ 919.8
Average headcount	7,649	6,739	910	7,549	6,570	979

Our average headcount in 2019 increased compared to 2018, principally in connection with expanding our manufacturing activities, increasing our research and development activities, and, to a lesser extent, the launching of Dupixent for asthma in the United States.

Operating expenses included a total of $105.8 million and $106.8 million in the second quarter of 2019 and 2018, respectively, and $213.7 million and $189.2 million in the first half of 2019 and 2018, respectively, of non-cash compensation expense related to employee stock options and restricted stock. In the first half of 2018, the change in our estimate of the number of stock options that were expected to be forfeited resulted in a higher reduction in the non-cash compensation expense compared to the first half of 2019.

Research and Development Expenses

The following table summarizes our estimates of direct research and development expenses by clinical development program and other significant categories of research and development expenses. Direct research and development expenses are comprised primarily of costs paid to third parties for clinical and product development activities, including costs related to preclinical research activities, clinical trials, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse. Indirect research and development expenses have not been allocated directly to each program, and primarily consist of costs to compensate personnel, overhead and infrastructure costs to maintain our facilities, and other costs related to activities that benefit multiple projects. Clinical manufacturing costs primarily consist of costs to manufacture bulk drug product (including pre-launch commercial supplies which were not capitalized as inventory) at our manufacturing facilities, as well as external drug filling, packaging, and labeling costs.

(In millions)	Three Months Ended June 30, 2019	Three Months Ended June 30, 2018*	Increase (Decrease)	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018*	Increase (Decrease)
Direct research and development expenses:						
Fasinumab	$ 59.6	$ 44.4	$ 15.2	$ 109.7	$ 99.1	$ 10.6
Libtayo (cemiplimab)	34.4	30.2	4.2	78.4	55.2	23.2
Dupixent (dupilumab)	19.6	31.1	(11.5)	45.3	56.9	(11.6)
Praluent (alirocumab)	11.3	12.8	(1.5)	21.5	29.6	(8.1)
Evinacumab	8.4	4.4	4.0	15.0	9.7	5.3
Up-front payments related to license and collaboration agreements	400.0	—	400.0	400.0	—	400.0
Other product candidates in clinical development and other research programs	82.3	43.0	39.3	171.3	85.4	85.9
Total direct research and development expenses	615.6	165.9	449.7	841.2	335.9	505.3
Indirect research and development expenses:						
Payroll and benefits	171.8	150.9	20.9	338.7	281.0	57.7
Lab supplies and other research and development costs	33.8	22.3	11.5	61.4	45.9	15.5
Occupancy and other operating costs	75.2	63.4	11.8	147.2	122.2	25.0
Total indirect research and development expenses	280.8	236.6	44.2	547.3	449.1	98.2
Clinical manufacturing costs	151.9	126.8	25.1	301.6	242.9	58.7
Total research and development expenses	$ 1,048.3	$ 529.3	$ 519.0	$ 1,690.1	$ 1,027.9	$ 662.2

* Certain prior year amounts have been reclassified to conform to the current year's presentation.

Research and development expenses in the second quarter and first half of 2019 included a $400.0 million up-front payment to Alnylam (see "Collaboration Agreements - Collaboration with Alnylam" above). Research and development expenses included non-cash compensation expense of $59.3 million and $59.6 million in the second quarter of 2019 and 2018, respectively, and $118.0 million and $100.4 million in the first half of 2019 and 2018, respectively.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A. "Risk Factors." There is also variability in the duration and costs necessary to develop a pharmaceutical product, potential opportunities and/or uncertainties related to future indications to be studied, and the estimated cost and scope of the projects. The lengthy process of seeking FDA and other applicable approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business. We are unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased in the second quarter and first half of 2019, compared to the same periods in 2018, primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Dupixent, and higher contributions to independent not-for-profit patient assistance organizations. Selling, general, and administrative expenses also included non-cash compensation expense of $37.7 million and $40.5 million in the second quarter of 2019 and 2018, respectively, and $81.5 million and $75.5 million in the first half of 2019 and 2018, respectively.

Cost of Goods Sold

In addition to costs in connection with producing commercial supplies for products that are sold by Regeneron in the United States (*i.e.*, EYLEA, Libtayo, and ARCALYST) and royalties we are obligated to pay on such sales, cost of goods sold includes period costs for our Limerick manufacturing facility. The increase in cost of goods sold for the three and six months ended June 30, 2019, compared to the same periods in 2018, was primarily due to our commercialization of Libtayo in the United States, including royalties to third parties and our obligation to pay Sanofi its share of Libtayo gross profits.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing primarily includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer. The increase in cost of collaboration and contract manufacturing for the three and six months ended June 30, 2019, compared to the same periods in 2018, was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent and higher expenses in connection with process validation at our Limerick manufacturing facility.

Other Income (Expense)

Other income (expense), net, decreased for the three and six months ended June 30, 2019, compared to the same periods in 2018, primarily due to the recognition of unrealized losses on equity securities, partly offset by increased interest income earned on available-for-sale debt securities primarily due to higher average investment balances.

Income Taxes

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except effective tax rate)	**2019**	**2018**	**2019**	**2018**
Income tax expense	$ 31.6	$ 104.7	$ 116.6	$ 212.1
Effective tax rate	14.1%	16.0%	15.1%	17.1%

Our effective tax rate for the three and six months ended June 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, stock-based compensation, federal tax credits for research activities, and, to a lesser extent, the foreign-derived intangible income deduction, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee. Our effective tax rate for the three and six months ended June 30, 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, the foreign-derived intangible income deduction, and federal tax credits for research activities.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	**June 30, 2019**	**December 31, 2018**	**Increase (Decrease)**
Financial assets:			
Cash and cash equivalents	$ 1,045.5	$ 1,467.7	$ (422.2)
Marketable securities - current	1,624.2	1,342.2	282.0
Marketable securities - noncurrent	2,884.6	1,755.0	1,129.6
	$ 5,554.3	$ 4,564.9	$ 989.4
Working capital:			
Current assets	$ 6,651.0	$ 6,447.6	$ 203.4
Current liabilities	1,713.1	1,442.8	270.3
	$ 4,937.9	$ 5,004.8	$ (66.9)

As of June 30, 2019, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Six Months Ended June 30, 2019 and 2018

(In millions)	June 30, 2019	June 30, 2018	Increase (Decrease)
Cash flows provided by operating activities	$ 1,085.3	$ 1,013.4	$ 71.9
Cash flows used in investing activities	$ (1,612.1)	$ (910.4)	$ (701.7)
Cash flows provided by financing activities	$ 104.6	$ 2.2	$ 102.4

Cash Flows from Operating Activities

Our net income of $654.2 million for the first half of 2019 included an up-front payment of $400.0 million made to Alnylam in April 2019 pursuant to our collaboration agreement (as described in "Collaboration Agreements - Collaborations with Alnylam" above) and $74.1 million related to unrealized losses (net) on equity securities (included in other non-cash items). Deferred taxes as of June 30, 2019 increased by $125.3 million, compared to December 31, 2018, primarily due to the tax treatment of the up-front payment made to Alnylam and non-cash compensation expense. Deferred revenue increased in the first half of 2019 primarily due to the receipt of a $461.9 million payment from Sanofi in connection with the Amended IO Discovery Agreement (as described in "Collaboration Agreements - Collaborations with Sanofi," above).

Cash Flows from Investing Activities

In the first half of 2019, we purchased $400.0 million of Alnylam common stock in connection with entering into the collaboration agreement. Capital expenditures were $168.9 million and $191.4 million in the first half of 2019 and 2018, respectively. We expect to incur capital expenditures of $380 million to $420 million for the full year of 2019 primarily in connection with expanding a portion of our manufacturing facilities, including an investment in fill/finish facilities and equipment, and laboratory expansion and renovations at our Tarrytown, New York facilities.

Sanofi Funding of Certain Development Costs

As described above in "Collaboration Agreements - Collaborations with Sanofi," effective January 7, 2018, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development and/or Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares (of which 1,042,732 shares remain available to be sold as of June 30, 2019) of our Common Stock directly or indirectly owned by Sanofi. During the first half of 2019, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 106,972 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded $44.0 million related to the shares received as Treasury Stock during the first half of 2019. In addition, during the first half of 2019, Sanofi elected to sell, and we elected to purchase (in cash), 24,143 shares of the Company's Common Stock in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments. Consequently, we recorded the cost of the shares received, or $10.0 million, as Treasury Stock during the first half of 2019.

Critical Accounting Policies and Use of Estimates

A summary of our critical accounting policies and use of estimates are presented in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (filed February 7, 2019). Except as described in Note 1 and Note 8 to our Condensed Consolidated Financial Statements included in this report related to the adoption of Accounting Standards Codification (ASC) 842, *Leases*, there were no material changes to our critical accounting policies and use of estimates during the six months ended June 30, 2019.

Future Impact of Recently Issued Accounting Standards

See Note 12 to our Condensed Consolidated Financial Statements for a summary of recently issued accounting standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (filed February 7, 2019). There have been no material changes to our market risks or to our management of such risks as of June 30, 2019.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 11 to our Condensed Consolidated Financial Statements included in this report.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products

We are substantially dependent on the success of EYLEA.

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the six months ended June 30, 2019 and 2018, EYLEA net sales in the United States represented 61% and 63% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

If we or our collaborators are unable to continue to successfully commercialize our products, our business, prospects, operating results, and financial condition will be materially harmed.

We expect that the degree of commercial success of our marketed products (in particular, EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) will continue to depend on many factors, including the following (as applicable):

- effectiveness of the commercial strategy in and outside the United States for the marketing of our products, including pricing strategy;
- sufficient coverage of, and reimbursement for, our marketed products by third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions, as well as U.S. and foreign payer restrictions on eligible patient populations and the reimbursement process (including drug price control measures that may be introduced in the United States by various federal and state authorities);
- our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development; and, in the case of EYLEA, the willingness of retinal specialists and patients to switch from Lucentis® (ranibizumab) or off-label use of repackaged Avastin® (bevacizumab) to EYLEA or to start treatment with EYLEA and the emerging new competition for EYLEA (discussed further under "*The commercial success of our products and product candidates is subject to strong competition* - Marketed Products - EYLEA" below);
- serious complications or side effects in connection with the use of our marketed products, as discussed under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below;
- maintaining and successfully monitoring commercial manufacturing arrangements for our marketed products with third parties who perform fill/finish or other steps in the manufacture of such products to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of our marketed products;
- the outcome of the pending patent infringement proceedings relating to EYLEA, Dupixent, and Praluent (described further in Note 11 to our Condensed Consolidated Financial Statements included in this report), and other risks relating to our marketed products associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below;
- the results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and studies of other products that could implicate an entire class of products or are perceived to do so; and
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including price reporting and other disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescribing practices and payer coverage.

More detailed information about the risks related to the commercialization of our marketed products is provided in the risk factors below.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or our collaborators commercialize. If we or our collaborators fail to maintain regulatory compliance for any of such products, the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or they commercialize (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) for the products' currently approved indications in the United States, EU, and other countries where such products are approved. If we or our collaborators fail to maintain regulatory compliance for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies, or for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain*"), the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales*" below.

Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales of our marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) in the United States are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of our marketed products in other countries are dependent, in large part, on similar reimbursement mechanisms and programs in those countries.

Our future revenues and profitability will be adversely affected in a material manner if such third-party payers do not adequately defray or reimburse the cost of our marketed products to patients. If these entities do not provide coverage and reimbursement with respect to our marketed products or provide an insufficient level of coverage and reimbursement, such products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payers more expensive for patients. Third-party payers may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply, and regulatory review of such products. Given cost sensitivities in many health care systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our marketed products, we must maintain, among other things, our FDA registration and our National Drug Code, formulary approval by pharmacy benefits managers, and recognition by insurance companies and the Centers for Medicare & Medicaid Services (CMS). There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage, as discussed further below) of our current and future marketed products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process, including by means of required prior authorizations and utilization management criteria, such as step therapy (*i.e.*, requiring the use of less costly medications before more costly medications are approved for coverage). Some states are also considering legislation that would control the prices and reimbursement of prescription drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform measures in the future that will impose additional constraints on prices and reimbursements for our marketed products.

Further, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation and policies designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer

patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. At the federal level, the current administration's budget proposal for fiscal year 2019 contained drug price control measures that have been subsequently rolled into the budget proposal for fiscal year 2020 and could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B (such as EYLEA), to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services has been soliciting feedback on some of these measures and may implement others impacting our business under its existing authority. CMS has also recently sought public comment on how best to leverage its authority provided under the Competitive Acquisition Program and introduce competition into Medicare Part B by allowing CMS to bring on vendors to negotiate payment amounts for Medicare Part B drugs. In addition, since January 1, 2019, CMS has allowed Medicare Advantage (MA) plans to use step therapy for Part B drugs (such as EYLEA). On October 25, 2018, President Trump announced that CMS was evaluating a program that proposes to set the Medicare payment amount for Part B single-source drugs and biologics to more closely align with international drug prices (also referred to as reference or international price index (IPI) drug pricing) and pay physicians and hospitals participating in such program a set drug add-on payment for administered drugs. CMS also issued an advance notice of proposed rulemaking that requested public comment on the proposed program, which is contemplated to initially cover fifty percent of Medicare Part B spending on separately payable Part B drugs (such as EYLEA), with the IPI-based price for each such drug to be phased in over a period of five years; notice of proposed rulemaking on this program is currently under review by the Office of Management and Budget. In addition, in July 2019, President Trump indicated that his administration was considering an executive order to establish a "most favored nation" pricing plan. While the scope and details of this contemplated executive action (including whether and how its mechanism may differ from that of the proposed IPI drug pricing program discussed above) are not clear, this seems to signal that the U.S. administration will continue to seek new measures to constrain drug costs and Medicare payments for drugs. Similarly, various members of the current U.S. Congress have indicated that lowering drug prices continues to be a legislative priority. At the state level, legislatures are becoming increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and price and marketing cost disclosure and transparency measures. In some cases, these measures are designed to encourage importation from other countries and bulk purchasing. A reduction in the availability or extent of reimbursement from U.S. government programs (including based on the proposals and initiatives described above) could have a material adverse effect on the sales of EYLEA or our other marketed products. Economic pressure on state budgets may also have a similar impact.

In addition, pharmacy benefit management companies often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one pharmacy benefit management company to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our marketed products. If our marketed products are not included within an adequate number of formularies, adequate reimbursement levels are not provided, the eligible insured patient population for our products is limited, or a key payer refuses to provide reimbursement for our products in a particular jurisdiction altogether, this could have a material adverse effect on our and our collaborators' ability to commercialize the applicable product.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our marketed products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our marketed products in foreign countries is limited or delayed.

The commercial success of our products and product candidates is subject to strong competition.

Marketed Products

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or

merge with larger pharmaceutical or biotechnology companies. There is significant actual and potential future competition for each of our marketed products.

EYLEA. The market for eye disease products is very competitive. For example, Novartis AG and Genentech/Roche are collaborating on the commercialization and further development of a vascular endothelial growth factor (VEGF) antibody fragment, Lucentis, for the treatment of various eye indications. Lucentis is approved in one or more jurisdictions for the treatment of wet AMD, macular edema following RVO (including CRVO and BRVO), DME, diabetic retinopathy, and mCNV. In addition, we are aware of several companies developing biosimilar versions of EYLEA. For example, Momenta Pharmaceuticals, Inc. (in partnership with Mylan N.V.) is developing M710 (currently in a pivotal trial in patients with DME). Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Formycon AG (in collaboration with Bioeq GmbH) is developing FYB201 (a Phase 3 trial in patients with wet AMD has been completed), Samsung Bioepis Co., Ltd. is developing SB11 (currently in a Phase 3 trial in patients with wet AMD), and Pfenex Inc. is developing PF582 (a Phase 1b/2a trial in patients with wet AMD has been completed).

Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, RVO, and diabetic retinopathy, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. Novartis is developing brolucizumab (RTH258), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A. Novartis announced in June 2017 that two Phase 3 studies of brolucizumab met their primary endpoint of non-inferiority to EYLEA and has indicated that it is targeting approval in wet AMD in the United States by year-end 2019. Allergan is developing abicipar pegol for wet AMD and related conditions and previously announced that two Phase 3 studies met their primary endpoint of non-inferiority to Lucentis. Chengdu Kanghong Pharmaceutical Industry Group Co., Ltd. is conducting non-inferiority Phase 3 trials in the United States and Europe comparing conbercept, an anti-VEGF fusion protein, against EYLEA in wet AMD. Conbercept is approved in the wet AMD and myopic choroidal neovascularization indications in China. Genentech/Roche is developing a port delivery system implant for ranibizumab (currently in a Phase 3 study in patients with wet AMD). Kodiak Sciences Inc. is developing KSI-301, an anti-VEGF biologic therapy that is conjugated to a phosphorylcholine-based biopolymer to extend its half-life, for wet AMD, DME, and RVO. A Phase 1 study of KSI-301 in patients with DME met its primary safety and tolerability endpoint, and Kodiak is conducting a Phase 1b open label study in patients with wet AMD, DME, and RVO. In addition, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, Ang2). Genentech/Roche is developing a bispecific antibody, faricimab (RG7716), that targets both VEGF and Ang2 for wet AMD and DME (currently in Phase 3 non-inferiority studies comparing faricimab against EYLEA in DME and wet AMD). Products that are being developed for use in combination with EYLEA and/or Lucentis may also pose a competitive threat. Opthea Limited is developing OPT-302, a VEGFR-3 large molecule trap in combination with Lucentis in a Phase 2 trial for wet AMD. Santen Pharmaceuticals Co. Ltd. (in partnership with TRACON Pharmaceuticals, Inc.) is developing DE-122, an anti-endoglin antibody in combination with Lucentis in a Phase 2 trial for wet AMD. Small-molecule tyrosine kinase inhibitors that have activity against VEGF may also compete against EYLEA, if approved for wet AMD and/or related conditions. Graybug Vision, Inc. is developing GB-102, an intravitreally administered depot formulation of the small molecule tyrosine kinase inhibitor, sunitinib, and indicated that it intends to initiate a Phase 2a trial in DME and a Phase 2b trial in wet AMD in the third quarter of 2019. Ocular Therapeutix, Inc. is developing OTX-TKI, a bioresorbable hydrogel formulated with tyrosine kinase inhibitor particles in an injectable fiber, for wet AMD and initiated a Phase 1 trial in February 2018. PanOptica, Inc. is developing PAN-90806, a topically administered tyrosine kinase inhibitor (Phase 1/2 trial for wet AMD completed). Competitors are also developing other eye-drop formulations, devices, oral therapies, and gene/cell therapies (such as REGENXBIO Inc.'s RGX-314) for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

Other competitive or potentially competitive products include Allergan plc's Ozurdex® (dexamethasone intravitreal implant) (approved by the FDA for the treatment of macular edema following RVO and for the treatment of DME) and Alimera Sciences Inc.'s Iluvien® (fluocinolone acetonide intravitreal implant) (approved by the FDA for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids.

In addition, ophthalmologists are using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, bevacizumab, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged bevacizumab presents a significant competitive challenge for EYLEA in these indications. Bevacizumab is also being evaluated in eye diseases in clinical trials in certain countries. Amgen Inc. (in collaboration with Allergan) has obtained regulatory approval of a biosimilar version of Avastin in the United States and the EU, and other competitors are also developing a biosimilar version of Avastin. Off-label use of any such biosimilar in one or more of the eye indications for which EYLEA is approved may put further pressure on the commercialization of EYLEA. Additionally, Outlook Therapeutics, Inc. is enrolling patients in Phase 3 trials in wet AMD for ONS-5010, a proprietary ophthalmic formulation of bevacizumab. The potential FDA approval of an ophthalmic formulation of bevacizumab may also affect market dynamics for EYLEA in the United States.

Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, but there is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye.

Dupixent. The market for Dupixent's current and potential future indications is competitive. In atopic dermatitis, Pfizer Inc.'s Eucrisa® (crisaborole), a topical ointment, competes with Dupixent and there are several other topical agents in development. In addition, a number of companies are developing antibodies against IL-13 for the treatment of atopic dermatitis, including LEO Pharma A/S (in collaboration with AstraZeneca PLC) with tralokinumab (currently in several Phase 3 trials) and Dermira, Inc. (in collaboration with Genentech/Roche) with lebrikizumab (Phase 2b trial completed). Antibodies targeting OX40 are also in development for atopic dermatitis, with Glenmark Pharmaceuticals Ltd., Kyowa Hakko Kirin Co., Ltd., and Kymab Ltd conducting Phase 2 trials of their respective programs (GBR-830, KHK4083, and KY-1005). Galderma S.A. has initiated Phase 3 trials of nemolizumab, an antibody against IL-31R, in atopic dermatitis. XBiotech Inc. has completed a Phase 2 trial of bermekimab, an anti-IL-1alpha antibody. Novartis, in partnership with MorphoSys, AG, has a Phase 2 trial in atopic dermatitis underway for MOR-106, an anti-IL-17C antibody. Kiniksa Pharmaceuticals, Ltd. has completed Phase 1 trials in atopic dermatitis for KPL-716, an antibody against the oncostatin M receptor beta. Orally administered small molecules are also being developed for atopic dermatitis, and, if approved, may compete with Dupixent in atopic dermatitis and other potential future indications. Several companies are studying JAK inhibitors for atopic dermatitis, including AbbVie Inc.'s upadacitinib, Pfizer's abrocitinib (PF-04965842) (a Phase 3 study reported in May 2019 to have met the primary endpoints), Eli Lilly and Company's baricitinib (two atopic dermatitis Phase 3 studies reported in February 2019 to have met their respective primary endpoints), and Asana BioSciences, LLC's ASN002 (currently in Phase 2 development).

In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor such as GlaxoSmithKline plc's Nucala® (mepolizumab), AstraZeneca's Fasenra® (benralizumab), and Teva's Cinqair® (reslizumab), all of which are approved for asthma in the United States and other jurisdictions. Novartis and Genentech/Roche's Xolair® (omalizumab) is also approved for asthma in multiple jurisdictions. In CRSwNP, competitors to Dupixent may include, if approved, Xolair (two CRSwNP Phase 3 trials reported in June 2019 to have met their respective primary endpoints) as well as Nucala and Fasenra (each in Phase 3 development for CRSwNP). Orally administered small molecule agents may also compete with Dupixent in asthma and potential future indications. For example, Novartis is developing fevipiprant, an oral prostaglandin D2 receptor 2 (CRTh2/DP2) antagonist, in multiple Phase 3 trials for asthma. Inhaled products may also compete with Dupixent in asthma and potential future indications, including Pieris Pharmaceuticals, Inc.'s PRS-060 (an anticalin being developed in partnership with AstraZeneca against IL-4R) and Novartis' CSJ117 (an antibody fragment against thymic stromal lymphopoietin).

There are several other potentially competitive products in development that may compete with Dupixent in both the atopic dermatitis and asthma indications, as well as potential future indications. For example, Amgen/AstraZeneca's tezepelumab, an antibody against thymic stromal lymphopoietin, or TSLP, is currently in Phase 3 development for asthma and Phase 2 development for atopic dermatitis. Antibodies against the IL-33 ligand or the IL-33 receptor (ST2) may also be competitive with Dupixent across multiple indications. Phase 2 trials are ongoing in atopic dermatitis and asthma for etokimab (ANB-020), an antibody against IL-33 developed by AnaptysBio, Inc. Genentech/Roche is developing RG6149, an anti-ST2 antibody, in Phase 2 trials for asthma and atopic dermatitis. GlaxoSmithKline plc (GSK) is developing GSK3772847, an anti-ST2 antibody, in a Phase 2 trial for asthma, and completed a Phase 1 trial that included atopic dermatitis patients. Eli Lilly is developing LY3375880, an anti-IL-33 antibody, in a Phase 2 trial for atopic dermatitis.

Praluent. Amgen's Repatha, an antibody targeting PCSK9, has received regulatory approvals in jurisdictions including the U.S., the EU, and Japan, and has captured a significant market share in certain jurisdictions. Repatha also received regulatory approval for cardiovascular risk reduction before Praluent in certain jurisdictions, including the U.S. In addition, LIB Therapeutics LLC is conducting Phase 2 studies with LIB003, a recombinant fusion protein targeting PCSK9, in atherosclerotic cardiovascular disease. Other companies with development programs for injectables against PCSK9 include Alnylam Pharmaceuticals, Inc. (in collaboration with The Medicines Company), which has Phase 3 trials underway with inclisiran, an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including oral products and vaccines. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including Praluent. These include bempedoic acid, which is being developed by Esperion Therapeutics, Inc. (submitted for regulatory review in the U.S. and EU).

Kevzara. Genentech/Roche and Chugai Pharmaceutical Co., Ltd. are marketing an antibody against IL-6R (Actemra® (tocilizumab)) for the treatment of rheumatoid arthritis that competes with Kevzara. In addition, several other companies, including R-Pharm JSC and BIOCAD, have antibodies against IL-6 or IL-6R in clinical development for rheumatoid arthritis. Biosimilar versions of Actemra may also compete with Kevzara, such as Mycenax Biotech Inc.'s LuciNex (a Phase 1 trial has been completed). Further, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz® (tofacitinib), Eli Lilly's Olumiant® (baricitinib), Gilead Sciences, Inc.'s filgotinib, Astellas Pharma Inc.'s peficitinib, and AbbVie's upadacitinib pose a competitive threat for Kevzara.

Libtayo. There are several competitors that are marketing or developing antibodies against PD-1 and/or PDL-1, including Bristol-Myers Squibb Company's Opdivo® (nivolumab), Merck & Co., Inc.'s Keytruda® (pembrolizumab), Roche's Tecentriq® (atezolizumab), AstraZeneca's Imfinzi® (durvalumab), Merck KGaA/Pfizer's Bavencio® (avelumab), Novartis' spartalizumab (PDR001), BeiGene Ltd.'s tislelizumab (BGB-A317), GSK's dostarlimab (TSR-042), Agenus Inc.'s AGEN2034, and Incyte Corporation's INCMGA0012.

Product Candidates

Our other late-stage and earlier-stage clinical candidates in development are all fully human antibodies, which were generated using our *VelocImmune* technology. Our antibody generation technologies and other late-stage and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody-based products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody-based product candidate against NGF. Competitors to evinacumab include Ionis Pharmaceuticals, Inc./Akcea Therapeutics, Inc.'s AKCEA-ANGPTL3-LRx, a ligand conjugated antisense drug against ANGPTL3, and Arrowhead Pharmaceuticals, Inc.'s ARO-ANG3, an RNAi therapeutic against ANGPTL3. We are also aware of several companies developing or marketing small molecules that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

We rely on our collaborations with Bayer and Sanofi for commercializing EYLEA and Dupixent, Praluent, Kevzara, and Libtayo, respectively.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA outside the United States. Under the terms of our license and collaboration agreement with Bayer (which is terminable by Bayer at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination), we rely on Bayer (and, in Japan, Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate) for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, while we have elected to co-promote Dupixent, Praluent, and Kevzara with Sanofi in the United States in accordance with the terms of our Antibody Collaboration, we continue to rely in part on Sanofi's sales and marketing organization in the United States for such products. Moreover, even though we lead commercialization efforts for Libtayo in the United States, Sanofi has exercised its option to co-promote Libtayo in the United States in accordance with the terms of our IO Collaboration. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of Dupixent, Praluent, Kevzara, or Libtayo (as applicable) may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent, Praluent, and Kevzara in the United States. For example, Sanofi records product sales for Dupixent, Praluent, and Kevzara in the United States, serves as the lead regulatory party for certain products and product candidates included in the Antibody Collaboration (*e.g.*, is responsible for regulatory filings and negotiations relating to such products and product candidates) in the United States, and may lead negotiations with payers relating to such products and product candidates. We also rely on Sanofi for sales, marketing, and distribution of Dupixent, Praluent, Kevzara, and Libtayo in countries outside the United States.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. We have limited commercial capabilities outside the United States and would have to

develop or outsource these capabilities. Therefore, termination of the Bayer collaboration agreement, our Antibody Collaboration, or our IO Collaboration would create substantial new and additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see "Risks Related to Our Reliance on Third Parties - *If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed*" below and "Risks Related to Our Reliance on Third Parties - *If our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed*" below.

Sales of our marketed products recorded by us and our collaborators could be reduced by imports from countries where such products may be available at lower prices.

Our sales of products we commercialize in the United States and our collaborators' sales of products they commercialize under our collaboration agreements with them in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under the relevant collaboration agreements and, therefore, our results of operations) may be reduced if the applicable product is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or otherwise alter the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. Similarly, under our Antibody Collaboration and IO Collaboration with Sanofi, pricing and reimbursement for the products commercialized thereunder outside the United States are the responsibility of Sanofi. Prices for our marketed products in jurisdictions outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United States. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations.

We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture, market, and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payers, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.

We sell EYLEA and Libtayo in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the six months ended June 30, 2019, product sales to two customers accounted on a combined basis for

89% of our total gross product revenue. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA and Libtayo will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA and Libtayo to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and do not currently have an organization for the sales, marketing, and distribution of marketed products outside the United States. There may be circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to exercise our option to co-promote a product outside the United States or commercialize a particular product independently; we are unable to find an appropriate collaborator; or our existing collaborator decides not to opt in, decides to opt out, or breaches its obligations to us with respect to a particular product.

In order to commercialize any products outside the United States, we must build our sales, marketing, distribution, managerial, and other non-technical capabilities in the relevant markets or make arrangements with third parties to perform these services, which would likely be expensive and time consuming and could delay product launch in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop commercial capabilities outside the United States within an acceptable time frame or at all. These and other difficulties relating to commercializing our products outside the United States may severely harm our business, prospects, operating results, and financial condition.

Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products

If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.

We cannot sell or market products without regulatory approval. If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products (or are materially delayed in doing so), the value of our Company and our business, prospects, operating results, and financial condition may be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

In certain instances (such as when we use a biomarker-based test to identify and enroll specific patients in a clinical trial), regulatory approval of a companion diagnostic to our therapeutic product candidate may be required as a condition to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. Its ability to do so has been enhanced by the Food and Drug Administration Amendments Act of 2007, pursuant to which the FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. Standard review can be accomplished in a 10-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within six months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. Even if any of our applications receives a priority review designation, we may not ultimately be able to obtain approval of our application within a time frame consistent with the FDA's stated review goals or at all, and such designation may not actually lead to a faster development or regulatory review or approval process.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional inspections or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. For additional information, see "Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.*" Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates), difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to the FDA's Good Laboratory Practices (GLPs) or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

Furthermore, some of our products and product candidates (such as Libtayo and Dupixent) are studied in combination with agents and treatments developed by us or our collaborators. There may be additional risks and unforeseen safety issues resulting from such combined administration, any of which may materially adversely impact clinical development of these product candidates and our ability to obtain regulatory approval.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our Company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness, and clinical trials evaluating our product candidates failed to meet the relevant endpoints. For example, in August 2017, we reported that the Phase 3 study evaluating suptavumab, an antibody to RSV, did not meet its primary endpoint of preventing medically-attended RSV infections in infants; as a result, we have discontinued further clinical development of this antibody. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval.

Many of our clinical trials are conducted under the oversight of independent Data Monitoring Committees (DMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible DMCs based on their review of such interim trial results. For example, in April 2018, the DMC monitoring the ongoing safety and efficacy of our Phase 3 clinical trials of fasinumab recommended that the higher dose-regimens be discontinued based on the risk-benefit assessment and that the program may continue with lower dose-regimens of fasinumab. As a result, the ongoing osteoarthritis trials have been modified accordingly and we discontinued dosing patients in the clinical study of fasinumab in chronic low back pain in patients with concomitant osteoarthritis of the knee and hip since this study was using only higher doses. The recommended termination or material modification of any of our ongoing late-stage clinical trials by a DMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our antibody-based product candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our Company.

Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

With respect to EYLEA, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize EYLEA. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like aflibercept (such as intraocular inflammation (IOI), sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), which can cause injury to the eye and other complications. The side effects previously reported for EYLEA include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. In addition, commercialization of EYLEA or our other products may be impacted by actions of third parties on which we rely, such as manufacturers of syringes or other devices used in the administration of our products. For example, in February 2018, we issued a letter to healthcare professionals providing updated guidance relating to reports of IOI following EYLEA injections. In this letter, we noted that while our review did not identify any association of IOI rates with the EYLEA drug itself, an association was seen with certain batches of the syringe that were included in specific lots of final packaged EYLEA kits. These and other complications or issues or side effects could harm further development and/or commercialization of EYLEA.

Dupixent is being studied in additional indications, as shown in the table under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Programs in Clinical Development." There is no guarantee that marketing approval of Dupixent in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include hypersensitivity reactions, conjunctivitis and keratitis, injection-site reactions, eye and eyelid inflammation, cold sores, oropharyngeal pain, and eosinophilia. These and other complications or side effects could harm further development and/or commercialization of Dupixent.

Libtayo is also being studied in additional indications, as shown in the table under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Programs in Clinical Development." There is no guarantee that marketing approval of Libtayo in any of these indications will be successfully obtained. The side effects previously reported for Libtayo include certain immune-mediated adverse reactions, such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea.

There also are risks inherent in subcutaneous injections (which are used for administering most of our antibody-based products and product candidates, including Dupixent, Praluent, and Kevzara), such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. These and other complications or side effects could harm further development and/or commercialization of our antibody-based products and product candidates utilizing this method of administration, including Dupixent, Praluent, or Kevzara.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross-react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so neutralizing antibodies may be detected at a later date, in some cases even after pivotal clinical trials have been completed.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody-based product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Many of our products are intended to be used and, if approved, our product candidates may be used in combination with drug-delivery devices, which may result in additional regulatory and other risks.

Many of our products (including Dupixent, Praluent, and Kevzara) are used and some of our products (including EYLEA) and product candidates may be used, if approved, in combination with a drug-delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. The success of our product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application and the additional risks resulting from a product candidate's designation as a combination product discussed below, our product candidates used with such drug-delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. The FDA review process and criteria for such applications is not a well-established area, which could also lead to delays in the approval process. In addition, some of these drug-delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply the devices; to conduct the studies required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our Company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic, or device. The determination whether a product is a combination product or two separately regulated products is made by the FDA on a case-by-case basis. Although a single marketing application is generally sufficient for the approval, clearance, or licensure of a combination product, the FDA may determine that separate marketing applications are necessary. In addition, submitting separate marketing applications may be necessary to receive some benefit that accrues only from approval under a particular type of application. This could significantly increase the resources and time required to bring a particular combination product to market.

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our Company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 2,264,163 is the subject of opposition proceedings in the European Patent Office (EPO) (currently pending before its Boards of Appeal), as described in Note 11 to our Condensed Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (USPTO), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review or *inter partes* review under the America Invents Act of 2011 or *ex parte* reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We also currently hold issued trademark registrations and have trademark applications pending in the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering, or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected.

We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others (including those relating to trademarks, copyrights, and trade secrets). Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody-based products made using our *VelocImmune* technology, or any other of our technologies, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we and/or our collaborator Sanofi are currently party to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent and patent infringement proceedings relating to Dupixent, as described in Note 11 to our Condensed Consolidated Financial Statements. In addition, we are currently party to patent infringement proceedings initiated by us relating to our patents that concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Note 11 to our Condensed Consolidated Financial Statements.

We are aware of patents and pending patent applications owned by others that respectively claim antibodies to IL-4R and methods of treating conditions including atopic dermatitis and asthma with such antibodies; antibodies to IL-6R and methods of treating conditions including rheumatoid arthritis with such antibodies; antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies; and antibodies to PD-1 and methods of treating cancer with such antibodies. In addition to Dupixent (dupilumab), Praluent (alirocumab), Kevzara (sarilumab), and Libtayo (cemiplimab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF, and evinacumab, an antibody to ANGPTL3.

Although we do not believe that any of our products or our late-stage antibody-based product candidates infringe any valid claim in these patents or patent applications, these other parties could initiate lawsuits for patent infringement and assert that their patents are valid and cover our products or our late-stage antibody-based product candidates, similar to the patent infringement proceedings referred to above. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our products or product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our products or product candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our products or product candidates infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. For example, in August 2018, we and Sanofi entered into a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, and Ono Pharmaceutical to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business.

Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "*If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed*," the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic, biosimilar, and/or interchangeable versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act (PPACA), there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened if, for example, the PPACA is amended.

A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. As discussed under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to strong competition*" above, there are several companies developing biosimilar versions of EYLEA. The loss of market exclusivity for a product (such as EYLEA) would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

We rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to continue to successfully commercialize EYLEA, to successfully commercialize Dupixent, Praluent, Kevzara, and Libtayo and, if approved, our product candidates or other indications for our marketed products, and to advance our clinical pipeline.

We have large-scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. Our manufacturing facilities would be inadequate to produce the active pharmaceutical ingredients of (a) our current marketed products, including EYLEA, Dupixent, Praluent, Kevzara, and Libtayo, and (b) our antibody-based product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody-based product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and late-stage product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, including EYLEA, Dupixent, Praluent, Kevzara, and Libtayo, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture products may be impaired if any of our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future, the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights

apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of EYLEA, Dupixent, Praluent, Kevzara, or Libtayo do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.

We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we or our collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results.

Third-party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, the manufacturing facilities of our collaborators, or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborators' facilities. We and our collaborators would be unable to manufacture these materials if the relevant facility were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, acts of war or terrorism, or other problems.

Many of our products and product candidates are very difficult to manufacture. As our products and product candidates are biologics, they require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us or our collaborators in a timely manner), could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time-consuming, and expensive to transfer our technology to our collaborators or contract manufacturers.

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties or our collaborators to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contaminations, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our or our collaborators' ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we or our collaborators are required to substitute for these sources to comply with European regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our collaborators and other third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. Our inability, or the inability of our collaborators and third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for Kevzara, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi fill-and-finish facility in Le Trait, France. While the BLA for Kevzara has since been approved by the FDA, this delayed the FDA approval of Kevzara. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of our collaborators or other third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Regulatory and Litigation Risks

If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell approved products in a way that violates federal or state healthcare laws, we may be subject to civil or criminal penalties.

The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA's review of promotional activities includes healthcare provider-directed and direct-to-consumer advertising as well as sales representatives' communications. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws. Recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal anti-kickback statute.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly

providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any "transfers of value" made to U.S. prescribers and certain other healthcare providers and teaching hospitals. Information provided by companies is aggregated and posted annually on an "Open Payments" website, which is managed by CMS, the agency responsible for implementing these disclosure requirements. We continue to dedicate significant resources to comply with these requirements and need to be prepared to comply with additional reporting obligations outside of the United States that may apply in the future. The PPACA also includes various provisions designed to strengthen fraud-and-abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, several states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to expand internationally, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, a number of which have yet to be fully implemented. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

The current U.S. administration and Congress could carry out significant changes in legislation, regulation, and government policy (including with respect to the possible repeal of all or portions of the PPACA, government reimbursement changes and drug price control measures, and changes in the existing treaty and trade relationships with other countries), as evidenced by statements and actions of President Trump and certain members of Congress (including those discussed above under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition*"). While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our products could adversely affect our business. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could materially and adversely affect our business.

Risks associated with our operations outside of the United States could adversely affect our business.

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "*Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*");
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

For example, in a referendum held in the United Kingdom, voters have approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, the British government has been negotiating the terms of the United Kingdom's future relationship with the EU. The outcome of these negotiations is uncertain, and we do not know to what extent Brexit (or the expectations that Brexit will occur) will ultimately impact the business and regulatory environment in the United Kingdom, the rest of the EU, or other countries. We have large-scale manufacturing operations in Limerick, Ireland and have also established an office in the vicinity of London. Changes impacting our ability to conduct business in the United Kingdom or other EU countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities that involve significant management judgment for uncertain tax positions. The Internal Revenue Service or other domestic or foreign taxing authorities may disagree with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country, changes in tax laws and regulations, and tax effects of the accounting for stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control). Changes in tax laws of various jurisdictions in which we do business could also result from the base erosion and profits shifting, or BEPS, recommendations by the Organization for Economic Co-operation and Development. If these recommendations (or other changes in law) were adopted by the countries in which we do business, it could adversely affect our provision for income tax and our current rate.

We face potential liability related to the privacy of health information and other personal information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with research institutions, including the Geisinger Health System, which are subject to such regulations. Regeneron is not currently classified as a covered entity or business associate under HIPAA and thus is not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Our clinical trial programs and research collaborations outside the U.S. (such as our consortium with a group of companies to fund the generation of genetic exome sequence data from the UK Biobank health resource) may implicate international data protection laws, including the European Union's General Data Protection Regulation (GDPR). The GDPR has created a range of new compliance obligations, including increased transparency requirements and new data subject rights. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). In addition to the GDPR, certain EU Member States have issued or will be issuing their own implementation legislation. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving privacy and data protection laws. Complying with varying jurisdictional requirements could increase the costs and complexity of compliance, including the new risk of substantial financial penalties for data breach or improper processing of personal data under the GDPR. Failure by our collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business and could create liability for us.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health and other personal information. Moreover, patients about whom we or our collaborators obtain health or other personal information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm, prevent, or substantially increase the cost of marketing and sales of any affected products that we are able to commercialize. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Risks Related to Our Reliance on Third Parties

If our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.

We rely on funding and support from Sanofi to develop, manufacture, and commercialize certain of our products and product candidates. With respect to Dupixent, Praluent, Kevzara, and REGN3500, which we are co-developing with Sanofi under our Antibody Collaboration, Sanofi funds a significant portion of development expenses incurred in connection with the development of these products. In addition, we rely on Sanofi to lead much of the clinical development efforts, assist with or lead efforts to obtain and maintain regulatory approvals, and lead the commercialization efforts for these products and product candidates.

As a result of the amendment and restatement of our IO Discovery and Development Agreement with Sanofi (which forms part of our IO Collaboration), we fund and conduct on our own all research, development, manufacturing, and commercialization activities to support all of our immuno-oncology product candidates other than REGN4018 and REGN5458, unless we enter into arrangements with other parties. In addition, if Sanofi does not elect to co-develop REGN4018 or REGN5458 under our IO Collaboration, or opts out of their development under our IO Collaboration, we will be required to fund and conduct on our own all such efforts to support those product candidates, unless we enter into arrangements with other parties.

If Sanofi elects to co-develop REGN5458 and/or REGN4018 under our IO Collaboration, Sanofi will initially fund almost all of the development expenses incurred in connection with the development of REGN5458, for which Sanofi will be the principal controlling party, and half of the development expenses incurred in connection with the clinical development of REGN4018, for which we will be the principal controlling party. Under our IO Collaboration, Sanofi also funds half of the development expenses incurred in connection with the clinical development of Libtayo, subject to an agreed-upon development budget. In addition, for REGN5458, we will rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we will rely on Sanofi to lead (i) the commercialization efforts in the United States for REGN5458 and (ii) the commercialization efforts outside the United States to support Libtayo, REGN4018, and REGN5458.

If Sanofi terminates the Antibody Collaboration or the IO Collaboration or fails to comply with its payment obligations under any of our collaborations, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. If Sanofi does not perform its obligations with respect to the product candidates that it elects to co-develop, our ability to develop, manufacture, and commercialize these product candidates will be significantly adversely affected. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for products commercialized under our Antibody Collaboration, such as Dupixent, Praluent, and Kevzara, or our IO Collaboration, such as Libtayo (see also "Risks Related to Commercialization of Products - *If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Antibody Collaboration or the IO Collaboration would create substantial new and additional risks to the successful development and commercialization of (i) Dupixent, Praluent, and Kevzara and (ii) Libtayo, respectively, particularly outside the United States.

If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed.

We rely heavily on Bayer with respect to the commercialization of EYLEA outside the United States. Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to commercialize EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the commercialization of EYLEA outside the United States and result in substantial additional costs and/or lower revenues to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also "Risks Related to Commercialization of Products - *If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA outside the United States.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi, Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third-party manufacturers, fill/finish providers, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of our marketed products and our late-stage product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner (including as a result of its inability to perform due to financial or other relevant constraints) or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators'

arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; and George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses, which may impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property, result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Such disruptions and breaches of security could result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing

If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.

If we cannot sustain profitability, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our sales of EYLEA, our share of the profits from Bayer's sales of EYLEA outside the United States, funding we receive under our collaboration agreements, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the commercialization of our marketed products and the potential commercial launches of our product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody-based product candidates we are developing on our own (without a collaborator), and expenses for which we are responsible in accordance with the terms of our collaboration agreements.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable terms or at all. For example, in March 2017, we completed a $720.0 million lease financing for our existing corporate headquarters and other rentable area consisting of approximately 150 acres of predominately office buildings and laboratory space located in the towns of Mount Pleasant and Greenburgh, New York, which will become due and payable in full on the five-year anniversary of the closing date unless extended with the consent of all the participants and subject to certain other conditions. Our ability to refinance or to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of our marketed products, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

Changes in foreign currency exchange rates could have a material adverse effect on our operating results.

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our Company.

Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.

As of June 30, 2019, we had $1,045.5 million in cash and cash equivalents and $4,508.8 million in marketable securities (including $414.0 million in equity securities). Our investments consist primarily of debt securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- net product sales of our marketed products (as recorded by us or our collaborators), in particular EYLEA, Dupixent, and Libtayo, as well as our overall operating results;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and the market share for, our marketed products, especially EYLEA, Dupixent, and Libtayo;
- whether our net product sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the EPO and in the USPTO;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management companies) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding (*i.e.*, a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient);
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders. As a result, the public float of our Common Stock (*i.e.*, the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of June 30, 2019, our five largest shareholders (including our largest shareholder Sanofi) plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 44.7% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2019. As of June 30, 2019, Sanofi beneficially owned 23,523,269 shares of our Common Stock, representing approximately 21.8% of the shares of Common Stock then outstanding. Under our January 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time are subject to a "lock-up" and may not be sold until December 20, 2020 (other than with respect to an aggregate of up to 1,042,732 shares, as to which we have agreed to waive the lock-up during the term of the letter agreement with Sanofi described below under "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management*" and which currently remain available to be sold in accordance with the letter agreement). These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our Company. If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market (including, in the case of Sanofi, as a result of the lock-up waiver referred to above), or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of June 30, 2019, holders of Class A Stock held 15.1% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of June 30, 2019:

- our current executive officers and directors beneficially owned 9.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2019, and 20.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2019; and
- our five largest shareholders (including our largest shareholder Sanofi) plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 44.7% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2019. In addition, these five shareholders plus our Chief Executive Officer held approximately 50.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of June 30, 2019.

Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our Company, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

In addition, we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as (other than during the term of the letter agreement described below) Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition of 20% of our outstanding shares of Class A Stock and Common Stock (taken together) (which occurred in April 2014), and (ii) 25% of our outstanding shares of Class A Stock and Common Stock (taken together) (Highest Percentage Threshold). This designee is required to be "independent" of our Company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant

of Sanofi. The current Sanofi designee, N. Anthony Coles, M.D., is a Class II director whose current term expires at the 2020 annual shareholder meeting.

Effective January 7, 2018, we and Sanofi and certain of Sanofi's direct and indirect subsidiaries entered into a letter agreement in connection with (a) the increase of the development budget amount for Libtayo set forth in the IO License and Collaboration Agreement and (b) the allocation of additional funds to certain proposed activities relating to the Dupilumab/REGN3500 Eligible Investments. Pursuant to the letter agreement, we have agreed, among other things, to grant a limited waiver of Sanofi's obligation to maintain the Highest Percentage Threshold during the term of the letter agreement in order to allow Sanofi to satisfy in whole or in part (a) its funding obligations with respect to the Libtayo development costs under the IO License and Collaboration Agreement for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to 800,000 shares of our Common Stock directly or indirectly owned by Sanofi (of which 477,641 currently remains available) and (b) its funding obligations with respect to the costs incurred by or on behalf of the parties to the Antibody License and Collaboration Agreement with respect to the Dupilumab/REGN3500 Eligible Investments for the quarterly periods commencing on January 1, 2018 and ending on September 30, 2020 by selling up to 600,000 shares of our Common Stock directly or indirectly owned by Sanofi (of which 565,091 currently remains available). If Sanofi desires to sell shares of our Common Stock during the term of the letter agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. In addition, we and Sanofi have agreed that, upon termination of the letter agreement, the amended and restated investor agreement will be amended to define "Highest Percentage Threshold" as the lower of (i) 25% of our outstanding shares of Class A Stock and Common Stock (taken together) and (ii) the higher of (a) Sanofi's percentage ownership of Class A Stock and Common Stock (taken together) on such termination date and (b) the highest percentage ownership of our outstanding shares of Class A Stock and Common Stock (taken together) Sanofi attains following such termination date.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements, could deter, delay, or prevent an acquisition or other "change of control" of us and could adversely affect the price of our Common Stock.

Our certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our Company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual shareholder meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our Company and an "interested shareholder," a plan of merger or consolidation of our Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.*"

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our Company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our License and Collaboration Agreement with Sanofi relating to our Antibody Collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement

providing for a change of control involving us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our Company.

Similarly, pursuant to our 2016 ANG2 license and collaboration agreement with Bayer (which was terminated on November 1, 2018 by agreement of the parties but whose "standstill" provisions continue to be in effect as described below), Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of our Company or acquiring more than 20% of our outstanding Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) November 1, 2023; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our Company; (iii) the acquisition by a third party or a group of third parties (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer; or (v) other specified events, such as a liquidation or dissolution of our Company.

Further, pursuant to the 2016 collaboration agreement between us and Teva, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of our Company or acquiring more than 5% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the acquisition by a third party or a group of third parties of more than 30% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (v) the date of any issuance of shares of capital stock by us that would result in another party having more than 10% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Teva; or (vi) other specified events, such as a liquidation or dissolution of our Company.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our Company. Also, equity awards issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, our 2014 Long-Term Incentive Plan, and our Amended and Restated 2014 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our Company, as defined in the plans. Further, under the amended and restated investor agreement between us and Sanofi, we are required to appoint an individual agreed upon by us and Sanofi to our board of directors and to use our reasonable efforts to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains a specified equity interest in us. As described above under "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management*," a Sanofi designee currently serves on our board of directors. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

The following table reflects shares of Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under one of our long-term incentive plans in the second quarter of 2019.

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
6/1/2019–6/30/2019	30	$ 307.36	—	—

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1	Amended and Restated Participation Agreement, dated as of May 2, 2019, by and among Old Saw Mill Holdings LLC, as lessee; Bank of America, N.A., as administrative agent; BA Leasing BSC, LLC, as lessor; and the lenders party thereto from time to time. (Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. (the "Registrant"), filed May 3, 2019.)
10.2	Amended and Restated Lease and Remedies Agreement, dated as of May 2, 2019, between Old Saw Mill Holdings LLC, as lessee, and BA Leasing BSC, LLC, as lessor. (Incorporated by reference from the Form 8-K for the Registrant, filed May 3, 2019.)
10.3	Amended and Restated Guaranty, dated as of May 2, 2019, made by the Registrant, Regeneron Healthcare Solutions, Inc., and Regeneron Genetics Center LLC, as guarantors. (Incorporated by reference from the Form 8-K for the Registrant, filed May 3, 2019.)
10.4*	Master Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc.
10.4.1*	Form of Co-Co Collaboration Agreement (Exhibit B to Master Agreement contained in Exhibit 10.4).
10.4.2*	Form of License Agreement (Exhibit C to Master Agreement contained in Exhibit 10.4).
10.5*	Investor Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc.
10.6	Stock Purchase Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Condensed Consolidated Balance Sheets as of June 30, 2019 and December 31, 2018; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2019 and 2018; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2019 and 2018; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2019 and 2018; and (v) the notes to the Registrant's Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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* Certain confidential portions of this exhibit were omitted in accordance with Item 601(b)(10) of Regulation S-K.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: August 6, 2019

By: /s/ Robert E. Landry

Robert E. Landry
Executive Vice President, Finance and
Chief Financial Officer
(Duly Authorized Officer)

Exhibit 10.4

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

MASTER AGREEMENT

between

ALNYLAM PHARMACEUTICALS, INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of April 8, 2019

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MASTER AGREEMENT

This Master Agreement (this "**Agreement**") is made and entered into as of April 8, 2019 (the "**Execution Date**") by and between Alnylam Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("**Alnylam**"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York ("**Regeneron**"). Alnylam and Regeneron are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Alnylam has scientific expertise and technology regarding the structure and use of therapeutic products that function through RNA interference;

WHEREAS, Alnylam owns or controls certain fundamental intellectual property relating to RNA interference;

WHEREAS, Regeneron has expertise in genetics research, including generating and analyzing genomic data, and identifying certain therapeutic targets, and in drug development and commercialization; and

WHEREAS, the Parties desire to collaborate on programs for the discovery, research, development and commercialization of siRNAs Directed to given Collaboration Targets as CNS Products, Eye Products or Liver Products, on the terms and subject to the conditions as set forth herein (each initially capitalized term as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Accounting Standards**" means, with respect to either Party, generally accepted accounting principles as applicable in the United States or International Financial Reporting Standards of the International Accounting Standards Board, in each case, as generally and consistently applied throughout such Party's organization. Each Party shall promptly notify the other Party in writing if such Party changes the Accounting Standards pursuant to which its records are maintained.

1.2 "**Acquired Party**" has the meaning set forth in Section 5.7.2(a).

1.3 "**Acquirer**" has the meaning set forth in Section 5.7.2(a).

1.4 "**Acquiring Party**" has the meaning set forth in Section 5.7.2(a).

1.5 "**Acquisition Product**" has the meaning set forth in Section 5.7.2(a).

1.6 "**Additional Alnylam In-Licenses**" means the agreements set forth in Section 3 of **Schedule 1.108**.

1.7 "**Adverse Ruling**" has the meaning set forth in Section 11.4.

1.8 "**Affiliate**" means, with respect to a Person, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person for so long as such Person controls, is controlled by or is under common control with such first Person, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management or policies of such entity.

1.9 "**Agreement**" has the meaning set forth in the preamble hereto.

1.10 "**Alliance Manager**" has the meaning set forth in Section 2.5.

1.11 "**Alnylam**" has the meaning set forth in the preamble hereto.

1.12 "**Alnylam Background Technology**" means, on a Program-by-Program basis, (a) Information that is necessary or reasonably useful to Exploit any Collaboration Product under such Program and (b) Patent Rights that Cover any Collaboration Product under such Program or the Exploitation of any Collaboration Product under such Program, in each case, ((a) and (b)), that are Controlled by Alnylam or its Affiliates as of the Execution Date or at any time thereafter until the

end of the Term, but excluding Alnylam Collaboration IP and Alnylam's interest in the Joint Collaboration IP.

1.13 "**Alnylam Background Technology Improvements**" means, on a Program-by-Program basis, any developments, enhancements, modifications or other improvements to, or progeny, mutants, fragments, or derivatives of, the Alnylam Background Technology that (a) are made by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with such Program under this Agreement, and (b) with respect to any of the foregoing constituting (i) Information, are not specifically and solely related to any Product-Specific Factor and (ii) Patent Rights, do not include any claim the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.14 "**Alnylam Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that is conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by individuals who are employees, agents or consultants of Alnylam or its Affiliates or its or their Sublicensees, in each case, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a). Alnylam Collaboration IP excludes Alnylam's interest in Joint Collaboration IP and any Regeneron Background Technology Improvements. Patent Rights constituting Alnylam Collaboration IP are either Alnylam Core Technology Patents or Alnylam Product-Specific Patents, as the case may be.

1.15 "**Alnylam Core Technology Know-How**" means, on a Program-by-Program basis, Alnylam Know-How other than Alnylam Product-Specific Know-How.

1.16 "**Alnylam Core Technology Patents**" means, on a Program-by-Program basis, Alnylam Patents (other than Alnylam Product-Specific Patents), including (a) with respect to a given Initial Program, those Patent Rights set forth on **Schedule 1.16** and (b) with respect to any New Program, those additional Patent Rights, if any, designated as an "Alnylam Core Technology Patent" for such New Program pursuant to Section 3.2.4(b).

1.17 "**Alnylam Delivery Patents**" has the meaning set forth in Section 7.2.3.

1.18 [***].

1.19 [***].

1.20 "**Alnylam Field Related Assets**" has the meaning set forth in Section 4.6.2.

1.21 "**Alnylam In-License**" means, on a Program-by-Program basis, any (a) Existing Alnylam In-License with respect to such Program; (b) Product-Specific In-License with respect to

such Program between Alnylam (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent that such agreement is designated as an Alnylam In-License pursuant to Section 5.5.1(a); or (c) Core Technology In-License with respect to such Program between Alnylam (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent such agreement is designated as an Alnylam In-License pursuant to Section 5.5.1(c).

1.22 "**Alnylam Indemnitees**" has the meaning set forth in Section 10.1.2.

1.23 [***].

1.24 "**Alnylam Know-How**" means (a) the Information included in the Alnylam Collaboration IP; (b) Alnylam's interest in the Information included in the Joint Collaboration IP; and (c) the Information included in Alnylam Background Technology or in any Alnylam Background Technology Improvements that is not in the public domain or otherwise generally known.

1.25 "**Alnylam Managed Patents**" has the meaning set forth in Section 9.2.4.

1.26 [***].

1.27 "**Alnylam Patents**" means (a) the Patent Rights included in the Alnylam Collaboration IP, (b) Alnylam's interest in the Joint Collaboration Patents and (c) the Patent Rights included in any Alnylam Background Technology or in any Alnylam Background Technology Improvements.

1.28 "**Alnylam Product-Specific Know-How**" means, on a Program-by-Program basis, Alnylam Know-How that is specifically and solely related to Product-Specific Factors for such Program.

1.29 "**Alnylam Product-Specific Patents**" means, on a Program-by-Program basis, the Alnylam Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor for such Program, including (a) with respect to a given Initial Program, those Patent Rights set forth on **Schedule 1.29** and (b) with respect to any New Program, those additional Patent Rights, if any, designated as an "Alnylam Product-Specific Patent" for such New Program pursuant to Section 3.2.4(b). For clarity, Alnylam Product-Specific Patents exclude [***].

1.30 "**Alnylam Reserved Target**" means [***].

1.31 "**Alnylam siRNA Platform**" means Alnylam Background Technology that relates generally to Alnylam's siRNA platform and is not primarily related to any Collaboration Product.

1.32 "**Alnylam Technology**" means, collectively, Alnylam Know-How and Alnylam Patents.

1.33 "**Annual Collaboration Target List**" has the meaning set forth in Section 3.2.3(b).

1.34 "**Annual Target Maximum**" means, for a given Calendar Year, a maximum of [***] Targets (or such greater number of Targets as may be mutually agreed to by the Parties for a given Calendar Year); provided that such maximum number of Targets shall be increased for a given Calendar Year as set forth in Section 3.2.3(b)(v), Section 3.4.1(f) or [***].

1.35 "**Antitrust Laws**" means the HSR Act, Sherman Act, as amended, the Clayton Act, as amended, the Federal Trade Commission Act, as amended, and all other Applicable Laws issued by a Governmental Authority that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening of competition.

1.36 "**API**" means any active pharmaceutical (including biological) ingredient or component (but excluding, for clarity, an adjuvant or excipient).

1.37 "**Applicable Law**" means applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time.

1.38 "**Arbitration Draft**" and "**Arbitration Drafts**" has the meaning set forth in Section 4.8.2(a).

1.39 "**Arbitrator**" has the meaning set forth in Section 4.8.2(b).

1.40 "**ASO**" means a single-stranded antisense oligonucleotide.

1.41 "**ASO Reagent**" means an ASO that is solely for research and does not require the design and characterization activities customarily required for a therapeutic candidate.

1.42 [***].

1.43 "**Biomarker**" means a defined and measurable molecular, histologic, radiographic or physiologic characteristic of patients or subjects.

1.44 "**Breaching Party**" has the meaning set forth in Section 11.4.

1.45 "**Business Day**" means a day other than a Saturday, Sunday or another day of the week on which commercial banks in New York, New York or Boston, Massachusetts, are authorized or required by Applicable Law to remain closed.

1.46 "**C5**" has the meaning set forth in the definition of "C5 Product."

1.47 "**C5 Agreements**" has the meaning set forth in Section 4.8.1.

1.48 "**C5 Agreements Term Sheet**" means the Term Sheet attached hereto as **Exhibit A**.

1.49 "**C5 Collaboration Agreement**" has the meaning set forth in Section 4.8.1.

1.50 "**C5 Combination License Agreement**" has the meaning set forth in Section 4.8.1.

1.51 "**C5 Combination Product**" means a Combination Product consisting of the C5 siRNA and the fully human monoclonal antibody targeting C5 being developed by or on behalf of Regeneron or its Affiliates and known as Pozelimab.

1.52 "**C5 Product**" means Cemdisiran (ALN-CC5) (the "**C5 siRNA**"), an siRNA therapeutic targeting the C5 component of the human complement pathway ("**C5**"), alone or in combination with one or more other APIs, in any and all forms, presentations, delivery systems, dosages, and formulations, but excluding the C5 Combination Product.

1.53 "**C5 siRNA**" has the meaning set forth in the definition of "C5 Product."

1.54 "**[***] Delivery Technology**" means [***] or (ii) is intended for delivery in the CNS or Eye, as applicable.

1.55 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.56 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.57 "**Candidate Discovery Plan**" means, on a Program-by-Program basis, the plan setting forth in reasonable detail the Development activities to support the generation, evaluation and optimization of Collaboration Products and the designation of Collaboration Products as Lead Candidates under such Program, including the specific Development activities to be performed up to identification of Lead Candidates and the anticipated timeline, which plan shall be in substantially the form of the template plan set forth on **Schedule 1.57** and shall allocate responsibility for such

Development activities between the Parties (provided that Alnylam shall always be responsible for those types of Development activities allocated to Alnylam as set forth in the template plan set forth on **Schedule 1.57**). The Candidate Discovery Plan for a given Program shall include (a) the Lead Candidate Criteria for such Program and (b) those types of Development activities outlined in **Schedule 1.57** (including certain activities designated to be performed by each of the Parties); provided that, for clarity, the Candidate Discovery Plan for a given Program may also include other Development activities to support the designation of Lead Candidates under the applicable Program. In no event shall the Candidate Discovery Plan include any activities for the general development of the Alnylam siRNA Platform unrelated to Collaboration Products. For the avoidance of doubt, the Candidate Discovery Plan shall not contain a budget.

1.58 "**Change of Control**" means, with respect to a Party (or its ultimate parent), (a) a merger, acquisition, consolidation or reorganization of such Party (or its ultimate parent) with a Third Party that results in the voting securities of such Party (or its ultimate parent) outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the "beneficial owner" (as such term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder (or, in each case, any successor thereto), except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party (or its ultimate parent), or (c) the sale or other transfer to a Third Party, whether directly or indirectly by a Party or an Affiliate thereof, of all or substantially all of such Party's (or its ultimate parent's) business.

1.59 "**Claim**" has the meaning set forth in Section 10.1.1.

1.60 "**Clinical Trial**" means (a) any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or Registration Enabling Trial, (b) such other tests and studies in human subjects that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Collaboration Product for an indication, including tests or studies that are intended to expand the Product Labeling for such Collaboration Product with respect to such indication and (c) any open label extension study of a Collaboration Product.

1.61 "**CNS**" means central nervous system, which includes the brain and spinal cord, dorsal root, trigeminal, pterygopalatine ganglia, submandibular ganglia, otic ganglia, and ciliary ganglia, but excluding peripheral nerves (other than dorsal root, trigeminal, pterygopalatine ganglia, submandibular ganglia, otic ganglia, and ciliary ganglia), the neuromuscular junction and muscle.

1.62 "**CNS Delivery Technology Development Plan**" has the meaning set forth in Section 3.1.2(a).

1.63 "**CNS Product**" means any product containing siRNA that has been specifically engineered or selected to be Directed to a Target as expressed in the CNS; provided that such product shall still be a "CNS Product" even if such product is also Directed to such Target as expressed in another organ(s) in the body.

1.64 "**CNS Program**" means a Program which has a CNS Target as the Collaboration Target under such Program.

1.65 "**CNS Target**" means a Target to which a CNS Product or anticipated CNS Product is Directed to. For clarity, references to CNS Product in this definition are used solely for purposes of initially identifying or selecting such Target as a Collaboration Target, Pre-Cleared Target, Designated Target or Listed Target hereunder, and otherwise the term "CNS Target" shall include such Target as expressed in the CNS or in any other organ(s).

1.66 "**Co-Co Collaboration Agreement**" means a Co-Co Collaboration Agreement in the form attached hereto as **Exhibit B**.

1.67 "**Co-Co Program**" means a Program for which the Parties enter into a Co-Co Collaboration Agreement in accordance with ARTICLE 4.

1.68 "**Collaboration Election Notice**" has the meaning set forth in Section 4.4.2.

1.69 "**Collaboration Election Period**" has the meaning set forth in Section 4.4.2.

1.70 "**Collaboration Product**" means any product containing an siRNA Directed to a given Collaboration Target as a CNS Product, Eye Product or Liver Product, as applicable, that is Developed under and in accordance with this Agreement, alone or in combination with one or more other APIs, in any and all forms, presentations, delivery systems, dosages, and formulations. For clarity, if a Collaboration Product that is a CNS Product, Eye Product or Liver Product, as applicable, has utility outside the CNS, Eye or Liver, respectively, then such uses outside the CNS, Eye or Liver, as applicable (including methods of treatment outside the CNS, Eye or Liver, as applicable), shall be permitted hereunder and such product containing an siRNA shall still be a Collaboration Product.

1.71 "**Collaboration Target**" means (a) each Initial Collaboration Target, and (b) each additional Target that is added as a "Collaboration Target" hereunder pursuant to Section 3.2; provided that (i) in the event that a given Collaboration Target is deemed to a be a "Terminated Target" pursuant to the terms of this Agreement, then such Target shall no longer be a Collaboration

Target, and (ii) "Collaboration Target" shall exclude (A) the Alnylam Reserved Target and (B) any Declined Target unless such Declined Target subsequently becomes a Collaboration Target as set forth in Section 3.2.3(b).

1.72 "**Combination Product**" means a Collaboration Product that is comprised of or contains an siRNA Directed to a given Collaboration Target as an API together with one or more other APIs and is sold either as (i) a fixed dose, (ii) separate doses in a single package, or (iii) separate doses in separate packages but for a single price.

1.73 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Collaboration Product, including activities related to marketing, promoting, distributing, and importing such Collaboration Product, and interacting with Regulatory Authorities regarding any of the foregoing after such Collaboration Product has received Regulatory Approval, including seeking Pricing Approvals, maintaining Regulatory Approvals, conducting Non-Approval Trials, commercial pharmacovigilance and health outcomes research and publishing scientific studies other than in connection with Development. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization.

1.74 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development or Manufacturing activities with respect to a Collaboration Product by a Party or other applicable activities by a Party hereunder, the carrying out of such activities in a diligent manner using efforts and resources [***] devote to products of similar market potential at a similar stage in development or product life, taking into account all scientific, commercial, and other factors that such Party and its Affiliates would take into account, including issues of safety and efficacy, expected and actual cost and time to develop, expected and actual profitability, expected and actual competitiveness of alternative products (including generic products) in the marketplace, the nature and extent of expected and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected likelihood of regulatory approval, the expected and actual reimbursability and pricing, and the expected and actual amounts of marketing and promotional expenditures required, [***], and provided that, for purposes of determining whether a Party's activities constitute "Commercially Reasonable Efforts," any products of such Party or its Affiliates [***].

1.75 "**Competing Product**" means, [***].

1.76 "**Competing Product Option**" has the meaning set forth in Section 5.7.2(c).

1.77 "**Competing Product Option Data Package**" means [***].

1.78 "**Competing Program**" has the meaning set forth in Section 5.7.2(a).

1.79 "**Competing Program Election Period**" has the meaning set forth in Section 5.7.2(d).

1.80 "**Competing Program Opt-Out Election Notice**" has the meaning set forth in Section 5.7.2(d).

1.81 "**Competitive Infringement**" has the meaning set forth in Section 7.3.1.

1.82 "**Confidential Information**" has the meaning set forth in Section 8.1.

1.83 "**Control**" means, with respect to a Party and any item of Information, Regulatory Documentation, material, Patent Right, or other intellectual property right, the possession by such Party or any of its Affiliates of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 5.1 or Section 5.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent Right, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party; provided, that, with respect to rights to any Third Party's Information, Patent Rights or other intellectual property rights that are licensed to, or otherwise obtained by, (a) a Party or its Affiliates pursuant to a Product-Related In-License entered into by such Party or any of its Affiliates after the Effective Date, or (b) Alnylam or its Affiliates pursuant to any Additional Alnylam In-License, such Third Party's Information, Patent Rights or other intellectual property rights shall be deemed not to be under the Control of such Party or its Affiliates, or Alnylam or its Affiliates, respectively, unless and until the agreement pursuant to which such rights are obtained becomes an In-License pursuant to Section 5.5.1(a), Section 5.5.1(c) or Section 5.5.2, as applicable.

1.84 "**Core Technology In-License**" means, on a Program-by-Program basis, a Product-Related In-License for such Program that is not a Product-Specific In-License.

1.85 "**Corporate Names**" means (a) with respect to Alnylam, the Trademarks and logos as Alnylam may designate in writing to Regeneron from time to time and (b) with respect to Regeneron, the Trademarks and logos as Regeneron may designate in writing to Alnylam from time to time.

1.86 "**Cover**" or "**Covering**" means, as to a product and Patent Rights, that, in the absence of a license granted under, or ownership of, such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights or, as to a pending claim included in such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights if such pending claim were to issue in an issued patent.

1.87 "**Damages**" has the meaning set forth in Section 10.1.1.

1.88 "**Data Package Delivery Date**" has the meaning set forth in Section 4.1.

1.89 "**Deadlocked Dispute**" has the meaning set forth in Section 2.2.3(a)(ii).

1.90 "**Declined Target**" means a Target that is deemed to be a "Declined Target" pursuant to Section 3.2.3(b); provided that if such Target subsequently becomes a Collaboration Target as set forth in Section 3.2.3(b), such Target shall no longer be a "Declined Target".

1.91 "**Default Notice**" has the meaning set forth in Section 11.4.

1.92 "**Designated Targets**" means [***].

1.93 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, Manufacturing scale-up, qualification and validation (but excluding such scale-up, qualification and validation with respect to establishing, or otherwise causing to become operational, any Manufacturing facilities), quality assurance/quality control, Clinical Trials, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing, medical affairs, medical information, medical education, health economic and outcomes research, market research, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. Development also includes the foregoing activities, if any, with respect to any devices (including diagnostics) designed for use with a Collaboration Product (which activities, if any, shall be set forth in the relevant Candidate Discovery Plan). Development does not include conducting Non-Approval Trials. When used as a verb, "**Develop**" means to engage in Development.

1.94 "**Development Data**" has the meaning set forth in Section 3.7.2.

1.95 "**Directed to**" means, with respect to siRNA and a Target (including a given Collaboration Target), that such siRNA binds to and interferes with the function of any messenger RNA encoded by such Target (including such Collaboration Target). For clarity, in the event an siRNA has been engineered to bind to and interfere with the function of any messenger RNA encoded by a particular Target other than a given Collaboration Target (and has not been engineered to bind to and interfere with the function of any messenger RNA encoded by a given Collaboration Target) but such siRNA additionally binds to or interferes with the function of any messenger RNA encoded by a given Collaboration Target, either directly or indirectly, then such product will not be deemed to be Directed to such Collaboration Target.

1.96 "**Divestment Period**" has the meaning set forth in Section 5.7.2(b).

1.97 "**Dollars**" or "**$**" means United States Dollars.

1.98 "**Drug Approval Application**" means a New Drug Application (an "**NDA**") as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application (an "**MAA**") filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.99 "**Effective Date**" has the meaning set forth in Section 12.18.

1.100 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.101 "**Equity Agreements**" means that certain (a) Stock Purchase Agreement entered into by Regeneron and Alnylam, on or about the date hereof (the "**Stock Purchase Agreement**"), and (b) Investor Agreement entered into by Regeneron and Alnylam, on or about the date hereof, in each case ((a)-(b)), as may be amended or restated from time to time.

1.102 "**European Union**" means the organization of member states of the European Union, as it may be constituted from time to time; provided that for the purposes of this Agreement the United Kingdom and any other country that is a member of the European Union on the Effective Date, shall be deemed to be a member of the European Union even if such country ceases to be a member of the European Union during the term of this Agreement.

1.103 "**Excluded Agreements**" means the agreements set forth on **Schedule 1.103**.

1.104 "**Excluded Collaboration Technology**" has the meaning set forth in Section 5.7.3(a).

1.105 "**Execution Date**" has the meaning set forth in the preamble hereto.

1.106 "**Executive Officer**" means, with respect to Alnylam, its Chief Executive Officer, and with respect to Regeneron, its Chief Executive Officer.

1.107 "**Existing Alnylam CMOs**" means each of the Third Party contract manufacturers set forth on **Schedule 1.107** and their respective Affiliates, successors and assigns.

1.108 "**Existing Alnylam In-Licenses**" means (a) with respect to a given Initial Program, the Third Party agreements identified in Part 1 of **Schedule 1.108**, (b) with respect to any New Program, any other Third Party agreements identified in Part 2 of **Schedule 1.108**, if any, that are

designated as "Existing Alnylam In-Licenses" for such New Program pursuant to Section 3.2.4(b), and (c) any Additional Alnylam In-License included within the definition of Existing Alnylam In-Licenses with respect to a given Program pursuant to Section 5.5.2. For clarity, the Existing Alnylam In-Licenses do not include the Excluded Agreements.

1.109 "**Existing Alnylam Third Party Agreements**" means the agreements identified in **Schedule 1.109**.

1.110 [***].

1.111 "**Existing Regeneron In-Licenses"** means (a) with respect to a given Initial Program, the Third Party agreements identified in Part 1 of **Schedule 1.111** and (b) with respect to any New Program, any other Third Party agreements identified in Part 2 of **Schedule 1.111**, if any, designated as an "Existing Regeneron In-Licenses" for such New Program pursuant to Section 3.2.4(b).

1.112 "**Existing Regeneron Third Party Agreements**" means the agreements identified on **Schedule 1.112**.

1.113 "**Existing Terminated Product**" has the meaning set forth in the definition of "Terminated Product."

1.114 "**Expert**" has the meaning set forth on **Schedule 1**.

1.115 "**Expert Dispute**" has the meaning set forth in Section 2.2.3(a)(iv).

1.116 "**Exploit**" means, with respect to a product, to make, have made, import, use, sell, or offer for sale, including to research (including pre-clinical and clinical research), Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of such product. When used as a noun, "**Exploitation**" means the act of Exploiting a product.

1.117 "**Eye**" means all parts of the eye, which for the avoidance of doubt, includes the cornea, iris, fovea, lens, macula, optic nerve, retina, pupil, sclera, and vitreous, and all periocular, periorbital and other accessary structures that support eye homeostasis, including conjunctiva, tissues of upper and lower eyelids, and fornices, meibomian glands, lacrimal glands and extraocular muscles.

1.118 "**Eye Delivery Technology Development Plan**" has the meaning set forth in Section 3.1.2(b).

1.119 "**Eye Product**" means any product containing siRNA that has been specifically engineered or selected to be Directed to a Target as expressed in the Eye; provided that such product shall still be an "Eye Product" even if such product is also Directed to such Target as expressed in another organ(s) in the body.

1.120 "**Eye Program**" means a Program which has an Eye Target as the Collaboration Target under such Program.

1.121 "**Eye Target**" means a Target to which an Eye Product or anticipated Eye Product is Directed to. For clarity, references to Eye Product in this definition are used solely for purposes of initially identifying or selecting such Target as a Collaboration Target, Pre-Cleared Target, Designated Target or Listed Target hereunder, and otherwise the term "Eye Target" shall include such Target as expressed in the Eye or in any other organ(s).

1.122 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.123 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.124 "**Field**" means all human diagnostic, prophylactic and therapeutic uses.

1.125 "**FTE Costs and Expenses**" means the sum of [***].

1.126 "**GalNAc**" means an N-acetylgalactosamine ligand.

1.127 "**Generic Product**" means, with respect to a particular Collaboration Product in a particular country in the Territory, any product that (a) is distributed by a Third Party under a separate Drug Approval Application approved by a Regulatory Authority in reliance, in whole or in part, on the Drug Approval Application for such Collaboration Product in such country (or on safety or efficacy data submitted in support of the Drug Approval Application for such Collaboration Product in such country), including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. § 355(b)(2) and 21 U.S.C. § 355(j), respectively), (ii) in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No. 726/2004 that relies for its content on any such provision) or (iii) in any other country or jurisdiction pursuant to an equivalent of such provisions or (b) is substitutable under Applicable Law for such Collaboration Product when dispensed without the intervention of a physician or other health care provider with prescribing authority.

1.128 "**Governmental Authority**" means any (a) federal, state, local, municipal, foreign or other government, (b) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, licensing body, officer, official, representative, organization, unit, body or entity and any court or other tribunal of competent jurisdiction (including any arbitration or other alternative dispute forum)), (c) supra-national or multinational governmental organization or body or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.129 "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.

1.130 "**In-License**" means, on a Program-by-Program basis, (a) any Alnylam In-License, and (b) any Regeneron In-License, in each case, for such Program.

1.131 "**In-License Payments**" means, [***].

1.132 "**IND**" means (a) an investigational new drug application filed with the FDA for authorization to commence Clinical Trials and its equivalent in other countries or regulatory jurisdictions, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.133 "**Indemnified Party**" has the meaning set forth in Section 10.2.1.

1.134 "**Indemnifying Party**" has the meaning set forth in Section 10.2.1.

1.135 "**Information**" means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and Materials, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays; and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.136 [***].

1.137 "**Initial Collaboration Target**" has the meaning set forth in Section 3.2.1.

1.138 "**Initial Programs**" has the meaning set forth in Section 3.2.1.

1.139 "**Initial Research Term**" means the period beginning on the Effective Date and ending on the later of:

1.139.1 the five (5) year anniversary of the Effective Date; and

1.139.2 the earliest of [***] and (b) the seven (7) year anniversary of the Effective Date.

In all cases, the Initial Research Term shall end no later than the date of termination of this Agreement in its entirety.

1.140 "**Initiation**" or "**Initiate**" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

1.141 "**Joint Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that are conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, jointly by individuals who are employees, agents or consultants of Alnylam or its Affiliates or its or their Sublicensees, on the one hand, and individuals who are employees, agents or consultants of Regeneron or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a) (the "**Joint Collaboration Patents**"). Joint Collaboration IP excludes any Alnylam Background Technology Improvements and any Regeneron Background Technology Improvements.

1.142 "**Joint Collaboration Patents**" has the meaning set forth in the definition of "Joint Collaboration IP."

1.143 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1.1.

1.144 "**JSC Dispute**" means a dispute that arises with respect to an issue within the jurisdiction of the JSC.

1.145 "**Knowledge**" means, with respect to a Party, the actual knowledge of such Party's internal legal department (including such legal department's intellectual property group), any employees of such Party who were directly involved in the negotiation of this Agreement with the other Party or any member of such Party's senior management.

1.146 "**Lead Candidate**" means, with respect to a given Program, a Collaboration Product that is Developed under such Program that (a) satisfies the Lead Candidate Criteria and is designated as a "Lead Candidate" in accordance with Section 4.2 or (b) is mutually designated by the Parties (or, with respect to an Eye Program, is designated by the Lead Party) as a "Lead Candidate" in accordance with Section 4.2.

1.147 "**Lead Candidate Criteria**" means, on a Program-by-Program basis, the criteria approved by the JSC [***] (or the Executive Officers or the Expert (or with respect to an Eye Program, as reasonably determined by the Lead Party) pursuant to Section 2.2.3(a)) for such Program (and deemed to be part of the Candidate Discovery Plan for such Program) to determine if a given Collaboration Product under such Program is ready to move into IND-enabling studies following completion of the activities under the Candidate Discovery Plan for such Program sufficient to advance such Collaboration Product to IND-enabling studies, as such criteria may be modified from time to time by the JSC [***] (or the Executive Officers or the Expert (or with respect to an Eye Program, as reasonably determined by the Lead Party) pursuant to Section 2.2.3(a)). The Lead Candidate Criteria shall be consistent with the criteria set forth on **Schedule 1.147**.

1.148 "**Lead Candidate Date**" has the meaning set forth in Section 4.2.

1.149 "**Lead Candidate Payment**" has the meaning set forth in Section 6.4.1(b).

1.150 "**Lead Continuation Party**" means, with respect to a given Program, the Party that is designated to have the right to be the "Licensee" under a License Agreement or the "Lead Party" under a Co-Co Collaboration Agreement, as applicable, for such Program in accordance with ARTICLE 4.

1.151 "**Lead Party**" means, for purposes of this Agreement [***].

1.152 "**Lead Patent Party**" means, for purposes of this Agreement [***].

1.153 "**Legal Dispute**" means any dispute related to a Party's alleged material breach of this Agreement or the validity, breach, termination or interpretation of this Agreement, or intellectual property-related disputes.

1.154 "**License Agreement**" means a License Agreement in the form attached hereto as **Exhibit C**.

1.155 "**Licensed Program**" means a Program for which the Parties enter into a License Agreement in accordance with ARTICLE 4.

1.156 "**Listed Target**" shall mean a Target that is designated as a "Listed Target" in accordance with Section 7.1.5(c).

1.157 "**Liver**" means the liver (including any cells constituting the liver itself or contained within the liver that are involved in the functional activities of the liver (e.g. metabolism, waste or bile excretion, immune defense, etc.)).

1.158 "**Liver Product**" means any product containing siRNA that has been specifically engineered or selected to be Directed to a Target as expressed in the Liver; provided that such product shall still be a "Liver Product" even if such product is also Directed to such Target as expressed in another organ(s) in the body.

1.159 "**Liver Program**" means a Program which has a Liver Target as the Collaboration Target under such Program.

1.160 "**Liver Target**" means a Target to which a Liver Product or anticipated Liver Product is Directed to. For clarity, references to Liver Product in this definition are used solely for purposes of initially identifying or selecting such Target as a Collaboration Target, Pre-Cleared Target, Designated Target, NASH Target, Reserved Liver Target or Regeneron Novel Liver Target hereunder, and otherwise the term "Liver Target" shall include such Target as expressed in the Liver or in any other organ(s).

1.161 "**MAA**" has the meaning set forth in the definition of "Drug Approval Application."

1.162 "**Major Event**" has the meaning set forth in Section 8.4.

1.163 "**Major Market Country**" means (a) each of the United States, Japan, France, Germany, Italy, the United Kingdom and Spain [***].

1.164 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, assembling, shipping, and holding of any Collaboration Product, or any intermediate thereof, and any placebo, as the case may be (including any devices or other delivery technologies that are packaged or distributed with a Collaboration Product), including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control, and management of any Third Party contractors conducting such activities.

1.165 "**Materials**" means all tangible compositions of matter, devices, articles of manufacture, assays, animal models, biological, chemical, or physical materials, and other similar materials, including cell lines and animal models; provided that "Materials" excludes Collaboration Products.

1.166 "**Merger Control Conditions**" means the following conditions, collectively: (a) the applicable waiting period under the HSR Act or any other applicable Antitrust Law will have expired or earlier been terminated; (b) no injunction (whether temporary, preliminary, or permanent) prohibiting, with respect to a Merger Control Filing pursuant to Section 4.9, the consummation of the transactions resulting from the execution of a License Agreement or Co-Co Collaboration

Agreement, as applicable, will be in effect; and (c) no judicial or administrative proceeding opposing, with respect to a Merger Control Filing pursuant to Section 4.9, the consummation of the transactions resulting from the execution of a License Agreement or Co-Co Collaboration Agreement, as applicable, will be pending.

1.167 "**Merger Control Filing**" means any filing with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the subject matter of this Agreement (or the execution of a License Agreement or Co-Co Collaboration Agreement, as applicable), together with all required documentary attachments thereto, or any other similar filing(s) or notification(s) required pursuant to any other Antitrust Law.

1.168 "**MicroRNA**" or "**miRNA**" means a structurally defined functional RNA molecule usually between nineteen (19) and twenty-five (25) nucleotides in length, which is derived from an endogenous, genetically-encoded non-coding RNA which is predicted to be processed into a hairpin RNA structure that is a substrate for the double-stranded RNA-specific ribonuclease drosha and subsequently is predicted to serve as a substrate for the enzyme dicer, a member of the RNase III enzyme family.

1.169 "**MicroRNA Mimic**" means a single-stranded or double-stranded oligonucleotide with the same or substantially similar base composition and sequence (including chemically modified bases) as a particular natural miRNA and which is designed to mimic the activity of such miRNA. For clarity, MicroRNA Mimic excludes a double-stranded oligonucleotide which functions or is designed to function as an siRNA.

1.170 "**NASH**" has the meaning set forth in the definition of "NASH Target."

1.171 "**NASH Target**" means a Liver Target that has a primary Therapeutic Rationale for the treatment or prevention of nonalcoholic steatohepatitis ("**NASH**"). For purposes of clarity, (a) the term "NASH Target" includes the Reserved NASH Targets, and (b) any Target (other than a Reserved NASH Target) that has a primary Therapeutic Rationale for any disease(s) or indication(s) other than NASH, including metabolic diseases (including diabetes), metabolic syndrome, dyslipidemia, obesity, diseases due to alcohol consumption, primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), hepatic infectious diseases, chronic active hepatitis, diseases of iron overload or diseases of copper overload, shall not be a NASH Target, even if such Target also has a potential Therapeutic Rationale for the treatment or prevention of NASH.

1.172 "**NDA**" has the meaning set forth in the definition of "Drug Approval Application."

1.173 "**New Alnylam External Program**" has the meaning set forth in Section 3.4.1(h).

1.174 "**New Program**" has the meaning set forth in Section 3.2.4(b).

1.175 "**New Program Permitted Dual Sequence Uses**" has the meaning set forth in Section 3.4.1(h).

1.176 "**Non-Acquiring Party**" has the meaning set forth in Section 5.7.2(a).

1.177 "**Non-Approval Trials**" means any surveys, registries and Clinical Trials not intended to gain Regulatory Approval or any additional labeled indications, excluding any open label extension studies of the Collaboration Products.

1.178 "**Non-Breaching Party**" has the meaning set forth in Section 11.4.

1.179 "**Non-CNS/Eye Delivery Technology**" means any delivery system that is specifically directed to an organ(s) other than to the CNS or Eye [***]. For clarity, Non-CNS/Eye Delivery Technology includes GalNAc but excludes [***] Delivery Technology.

1.180 "**Non-Liver Delivery Technology**" means any delivery system that is specifically directed to an organ(s) other than to the Liver and [***]. For clarity, Non-Liver Delivery Technology excludes GalNAc.

1.181 "**Novel Target Indication**" has the meaning set forth in the definition of "Regeneron Novel Liver Target."

1.182 "**Other Delivery Technology**" means any [***] delivery technology other than [***] Delivery Technology or Non-CNS/Eye Delivery Technology.

1.183 [***].

1.184 "**Out-of-Pocket Costs**" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the paying Party's Accounting Standards) by either Party or its Affiliates in connection with activities under this Agreement, excluding FTE Costs and Expenses.

1.185 "**Participating Party**" means, for purposes of this Agreement, Alnylam.

1.186 "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.187 "**Patent Rights**" means (a) all issued patents (including any extensions, restorations by any existing or future extension or registration mechanism (including patent term adjustments, patent term extensions, supplemental protection certificates or the equivalent thereof), substitutions, confirmations, re-registrations, re-examinations, and patents of addition); (b) patent applications (including all provisional applications, substitutions, requests for continuation, continuations,

continuations-in-part, divisionals and renewals); (c) inventor's certificates; and (d) all equivalents of the foregoing in any country of the world.

1.188 "**Permitted Alnylam Outside Product**" means, on a Program-by-Program basis, any [***].

1.189 [***] .

1.190 "**Permitted Claim Scope**" means [***].

1.191 "**Permitted Dual Sequence**" means, with respect to a given Collaboration Target, [***] "**Permitted Dual Sequence**" [***].

1.192 "**Permitted Dual Sequence Uses**" means, with respect to a given Permitted Dual Sequence, [***].

1.193 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.194 "**Phase 1 Clinical Trial**" means a human clinical trial of a Collaboration Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, or a similar clinical study prescribed by the applicable Regulatory Authorities, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(a), as amended.

1.195 "**Phase 2 Clinical Trial**" means a human clinical trial of a Collaboration Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, or a similar clinical study prescribed by the applicable Regulatory Authorities, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(b), as amended.

1.196 "**Phase 3 Clinical Trial**" means a human clinical trial of a Collaboration Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use and to determine warnings, precautions, and adverse reactions that are associated with such Collaboration Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Collaboration Product, including all tests and studies that are required by the FDA, pursuant to Applicable Law or otherwise.

1.197 "**Pre-Cleared Target**" means [***].

1.198 "**Pre-Existing Affiliates**" has the meaning set forth in Section 5.7.2(f).

1.199 "**Preliminary Pre-Clinical Plan**" has the meaning set forth in Section 4.4.1(c).

1.200 "**Pricing Approval**" means such approval, agreement, determination or governmental decision establishing prices for a Collaboration Product that can be charged to consumers and will be reimbursed by Regulatory Authorities in countries where Regulatory Authorities of such countries approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.201 "**Product Labeling**" means, with respect to a Collaboration Product in a country in the Territory, (a) the Regulatory Authority approved full prescribing information for such Collaboration Product for such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Collaboration Product in such country.

1.202 "**Product-Related In-License**" means, on a Program-by-Program basis, a license or other similar agreement with a Third Party (other than the Existing Alnylam In-Licenses and the Existing Regeneron In-Licenses) to license or obtain any similar right or interest in any (a) Information necessary or reasonably useful to perform any activities under a Candidate Discovery Plan for such Program or to achieve the objectives thereof or to Exploit any Collaboration Product under such Program or (b) Patent Right that Covers any Collaboration Product under such Program or the Exploitation thereof.

1.203 [***].

1.204 [***].

1.205 "**Product-Specific Factors**" means, on a Program-by-Program basis, [***].

1.206 "**Product-Specific Information**" has the meaning set forth in Section 8.1.

1.207 "**Product-Specific In-License**" means, on a Program-by-Program basis, a Product-Related In-License for Information that is primarily related to, or Patent Rights that primarily claim, Product-Specific Factors for such Program.

1.208 "**Program**" means, for a given Collaboration Target, the program undertaken by or on behalf of the Parties hereunder to Develop Collaboration Products Directed to such Collaboration Target in accordance with the Candidate Discovery Plan for such program through the designation of the first Lead Candidate Directed to such Collaboration Target. For the avoidance of doubt, (i) each Collaboration Target shall be the subject of a separate single Program and (ii) any activities undertaken pursuant to a License Agreement or Co-Co Collaboration Agreement shall not be part of the Program.

1.209 "**Program Assets**" has the meaning set forth in Section 4.6.1.

1.210 "**Program Data Package**" means, on a Program-by-Program basis, an information package delivered separately by each Party as set forth in Section 4.1 containing the following with respect to such Program: (a) with respect to a particular Program, (i) the set of all preclinical data and analyses (including electronic or other reasonable access to all raw data), and (ii) all CMC data, in each case, generated under the applicable Candidate Discovery Plan, (b) a description of any and all obligations that the Party (or its Affiliates) delivering the information package has to a Third Party, financial or otherwise, with respect to the Development, Manufacture or Commercialization of any Collaboration Product under such Program, (c) a list of any exceptions to any of such Party's representations or warranties set forth in the License Agreement or Co-Co Collaboration Agreement, as applicable, that such Party would need to include in the event that the Parties enter into a License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program, and (d) a draft of all other schedules and exhibits (to be prepared by such Party) to the License Agreement or Co-Co Collaboration Agreement, as applicable, as proposed by such Party in the event that the Parties enter into a License Agreement or Co-Co Collaboration Agreement, as applicable.

1.211 "**Proof of Principle**" means, with respect to a given Eye Program or CNS Program, the date the Clinical Trial results (e.g., key results memo containing tables, figures and listings) from the Proof of Principle Study for such Eye Program or CNS Program, as applicable, that are sufficient to demonstrate that the Proof of Principle Criteria have been successfully achieved for such Eye Program or CNS Program, as applicable, are made available to the JSC.

1.212 "**Proof of Principle Criteria**" means (a) with respect to each Eye Program, the criteria to be mutually agreed to by the Parties prior to the commencement of the first Phase 1 Clinical Trial for such Eye Program, and (b) with respect to each CNS Program, the criteria to be mutually agreed to by the Parties prior to the commencement of the first Phase 1 Clinical Trial for such CNS Program, in each case (a) and (b) where [***]) (each, a "**Relevant Study Cohort**"). The Parties acknowledge and agree that, on a Program-by-Program basis, the Proof of Principle Criteria for a given Eye Program or CNS Program shall at least include the following (but may not necessarily include more): [***]

1.213 "**Proof of Principle Milestone Payment**" has the meaning set forth in Section 6.5.

1.214 "**Proof of Principle Study**" means, on a Program-by-Program basis for Eye Products and CNS Products, a Clinical Trial conducted under a Co-Co Collaboration Agreement or License Agreement, as applicable, that is designed to meet the Proof of Principle Criteria and identified as a "Proof of Principle Study" in the Development Plan and Budget (as defined in the applicable Co-Co Collaboration Agreement) or as identified by the Licensee (as defined in the applicable License

Agreement) to the JSC pursuant to Section 3.3.2 of the License Agreement, as applicable, for such Program.

1.215 "**Proprietary Unlicensed Component**" means, with respect to a given Party, an Unlicensed Component that is (a) proprietary to such Party (or its Affiliate) or (b) otherwise controlled (through license or otherwise) by such Party (or its Affiliate).

1.216 [***] has the meaning set forth in Section 3.3.3(b).

1.217 "**Regeneron**" has the meaning set forth in the preamble hereto.

1.218 "**Regeneron Background Technology**" means, on a Program-by-Program basis, (a) Information that is necessary or reasonably useful to Exploit any Collaboration Product under such Program and (b) Patent Rights that Cover any Collaboration Product under such Program or the Exploitation of any Collaboration Product under such Program, in each case, ((a) and (b)), that are Controlled by Regeneron or its Affiliates as of the Execution Date or at any time thereafter until the end of the Term, but excluding Regeneron Collaboration IP and Regeneron's interest in the Joint Collaboration IP. Notwithstanding the foregoing, Regeneron Background Technology shall exclude (i) any Information related to any Unlicensed Component and (ii) any Patent Rights that Cover the composition or use or manufacture of any Unlicensed Component (alone or in combination).

1.219 "**Regeneron Background Technology Improvements**" means, on a Program-by-Program basis, any developments, enhancements, modifications or other improvements to, or progeny, mutants, fragments, or derivatives of, (x) the Regeneron Background Technology or (y) any Unlicensed Component Controlled by Regeneron or any of its Affiliates, that (a) are made by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with such Program under this Agreement, and (b) with respect to any of the foregoing constituting (i) Information, are not specifically and solely related to any Product-Specific Factor and (ii) Patent Rights, do not include any claim the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.220 [***].

1.221 "**Regeneron Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that is conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by individuals who are employees, agents or consultants of Regeneron or its Affiliates or its or their Sublicensees, in each case, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a). Regeneron Collaboration IP excludes Regeneron's interest in Joint Collaboration IP and any Alnylam Background Technology

Improvements. Patent Rights constituting Regeneron Collaboration IP are either Regeneron Core Technology Patents or Regeneron Product-Specific Patents, as the case may be.

1.222 "**Regeneron Core Technology Know-How**" means, on a Program-by-Program basis, Regeneron Know-How other than Regeneron Product-Specific Know-How.

1.223 "**Regeneron Core Technology Patents**" means, on a Program-by-Program basis, Regeneron Patents other than Regeneron Product-Specific Patents.

1.224 "**Regeneron Eye Program Discontinuation Notice**" has the meaning set forth in Section 4.3.2.

1.225 "**Regeneron In-License**" means, on a Program-by-Program basis, any (a) Existing Regeneron In-License with respect to such Program, (b) Product-Specific In-License with respect to such Program between Regeneron (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent that such agreement is designated as a Regeneron In-License pursuant to Section 5.5.1(a) or (c) Core Technology In-License with respect to such Program between Regeneron (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent such agreement is designated as a Regeneron In-License pursuant to Section 5.5.1(c).

1.226 "**Regeneron Indemnitees**" has the meaning set forth in Section 10.1.1.

1.227 "**Regeneron Know-How**" means (a) the Information included in the Regeneron Collaboration IP; (b) Regeneron's interest in the Information included in the Joint Collaboration IP; and (c) the Information included in any Regeneron Background Technology or in any Regeneron Background Technology Improvements that is not in the public domain or otherwise generally known.

1.228 "**Regeneron Mice**" means Regeneron's proprietary, genetically engineered mice, and any progeny of such mice (including cross-bred progeny resulting from producing a genetically engineered mouse by breeding or by using any portion of any of Regeneron's proprietary genetically engineered mice) or other mice derived therefrom.

1.229 "**Regeneron Novel Liver Target**" means [***].

1.230 "**Regeneron Patents**" means (a) the Patent Rights included in the Regeneron Collaboration IP; (b) Regeneron's interest in the Joint Collaboration Patents; and (c) the Patent Rights included in any Regeneron Background Technology or in any Regeneron Background Technology Improvements.

1.231 "**Regeneron Product-Specific Know-How**" means, on a Program-by-Program basis, Regeneron Know-How that is specifically and solely related to Product-Specific Factors for such Program.

1.232 "**Regeneron Product-Specific Patents**" means, on a Program-by-Program basis, the Regeneron Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor for such Program, including, with respect to any New Program, those additional Patent Rights, if any, designated as a "Regeneron Product-Specific Patent" for such New Program pursuant to Section 3.2.4(b).

1.233 "**Regeneron Technology**" means, collectively, Regeneron Know-How and Regeneron Patents.

1.234 "**Registration Enabling Trial**" means a human clinical trial (whether or not designated a Phase 3 Clinical Trial) of a Collaboration Product (a) the results of which, together with prior data and information concerning such Collaboration Product, are intended at the time such human clinical trial is Initiated to establish that such Collaboration Product is safe and effective for its intended use; and (b) that forms the basis (alone or with one or more additional Registration Enabling Trials) of an effectiveness claim in support of a Regulatory Approval for such Collaboration Product, in each case ((a) and (b)), as acknowledged in writing by the FDA for any human clinical trial that does not meet the criteria for a Phase 3 Clinical Trial at the time such human clinical trial is Initiated.

1.235 "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, or market a Collaboration Product in such country, including, where applicable, (a) Pricing Approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) labeling approval.

1.236 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Collaboration Product in the Territory.

1.237 "**Regulatory Documentation**" means all (a) applications (including all INDs and Drug Approval Applications and other major regulatory filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with

respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files.

1.238 "**Relevant Study Cohort**" has the meaning set forth in the definition of "Proof of Principle Criteria."

1.239 "**Requesting Party**" has the meaning set forth in Section 3.6.

1.240 "**Research Collaboration Termination Notice**" has the meaning set forth in Section 11.2.

1.241 "**Research Extension Fee**" [***] For clarity, the maximum Research Extension Fee payable shall be Four Hundred Million Dollars ($400,000,000).

1.242 "**Research Extension Option**" has the meaning set forth in Section 3.3.2.

1.243 "**Research Term**" means the Initial Research Term plus, if applicable, the Research Term Extension Period.

1.244 "**Research Term Extension Period**" means, if Regeneron exercises its Research Extension Option pursuant to Section 3.3.2, the period commencing at the end of the Initial Research Term and ending on the earlier of (a) the five (5) year anniversary of the end of the Initial Research Term, and (b) the termination of this Agreement in its entirety.

1.245 "**Research Term Tail**" means, on a Program-by-Program basis, the period commencing at the end of the Research Term [***].

1.246 "**Research Term Tail Election Period**" has the meaning set forth in Section 3.3.3(b).

1.247 "**Reserved Liver Target**" means each Target set forth on **Schedule 1.247**; provided that, (i) in the event that a given Reserved Liver Target becomes a Collaboration Target, then such Target shall no longer be a Reserved Liver Target (and shall instead be a Collaboration Target hereunder), (ii) in the event that a given Reserved Liver Target does not become a Collaboration Target prior to the end of the Research Term, then such Target shall no longer be a Reserved Liver Target as of the end of the Research Term, (iii) in the event that Regeneron or any of its Affiliates (alone or with one or more Third Party(ies)) develops, commercializes or manufactures for the purposes of development or commercialization a product that would have otherwise been in violation of Section 5.7.1(a) had such Reserved Liver Target been a Collaboration Target, then such Target shall no longer be a Reserved Liver Target, and Regeneron shall provide prompt notice of same to Alnylam, and (iv) Regeneron shall have the right to notify Alnylam in writing from time to time that a given existing Reserved Liver Target shall no longer be a Reserved Liver Target.

1.248 "**Reserved NASH Target**" means (a) each Target set forth on **Schedule 1.248** and (b) each other NASH Target that is designated as a "Reserved NASH Target" in accordance with Section 3.2.2(a); provided that, (i) in the event that a given Reserved NASH Target becomes a Collaboration Target, then such Target shall no longer be a Reserved NASH Target (and shall instead be a Collaboration Target hereunder), (ii) in the event that a given Reserved NASH Target does not become a Collaboration Target prior to the end of the Research Term, then such Target shall no longer be a Reserved NASH Target as of the end of the Research Term, (iii) in the event that Regeneron or any of its Affiliates (alone or with one or more Third Party(ies)) develops, commercializes or manufactures for the purposes of development or commercialization a product that would have otherwise been in violation of Section 5.7.1(a) had such Reserved NASH Target been a Collaboration Target, then such Target shall no longer be a Reserved NASH Target, and Regeneron shall provide prompt notice of same to Alnylam, and (iv) Regeneron shall have the right to notify Alnylam in writing from time to time that a given existing Reserved NASH Target shall no longer be a Reserved NASH Target.

1.249 "**siRNA**" means an oligonucleotide composition of native or chemically modified RNA that targets a gene through activation of the RNA interference pathway, and that is not a MicroRNA, MicroRNA antagonist or MicroRNA Mimic.

1.250 "**Stock Purchase Agreement**" has the meaning set forth in the definition of "Equity Agreements."

1.251 "**Sublicensed Party**" has the meaning set forth in Section 5.5.4.

1.252 "**Sublicensee**" means a Third Party that is granted, in accordance with this Agreement, a (sub)license by a Party or its Affiliates to intellectual property licensed under this Agreement by such Party or its Affiliates to, or to such Party and its Affiliates by, the other Party or its Affiliates, to Develop or Commercialize a Collaboration Product.

1.253 "**Sublicensor Party**" has the meaning set forth in Section 5.5.4.

1.254 "**Target**" means a human gene.

1.255 [***].

1.256 "**Term**" has the meaning set forth in Section 11.1.

1.257 "**Terminated Product**" means, with respect to a given Program, (a) any Collaboration Product that is the subject of Development under such Program by or on behalf of one or more Parties in the Territory as of the effective date of termination of this Agreement (with respect to a Program or in its entirety), but excluding any Proprietary Unlicensed Component of

either Party (or its Affiliate) (the Collaboration Products under this clause (a), an "**Existing Terminated Product**") or (b) any improvements, modifications or enhancements to such Collaboration Product, but excluding any Proprietary Unlicensed Component of either Party (or its Affiliate).

1.258 "**Terminated Program**" means a Program that is expressly designated as a "Terminated Program" pursuant to this Agreement. For clarity, once a Program is designated as a "Terminated Program" it shall no longer be a Program for purposes of this Agreement.

1.259 "**Terminated Target**" means a Collaboration Target that is deemed a "Terminated Target" pursuant to this Agreement. For clarity, once a Collaboration Target is deemed a "Terminated Target" it shall no longer be a Collaboration Target for purposes of this Agreement.

1.260 "**Territory**" means the entire world.

1.261 "**Therapeutic Rationale**" means, with respect to a given Target, that [***].

1.262 "**Third Party**" means any Person other than Alnylam, Regeneron and their respective Affiliates.

1.263 "**Third Party Acquisition**" has the meaning set forth in Section 5.7.2(a).

1.264 "**Third Party Infringement Action**" has the meaning set forth in Section 7.6.1.

1.265 "**Third Party Provider**" has the meaning set forth in Section 3.4.5.

1.266 "**Third Party Transaction**" means, with respect to a given Program, any transaction pursuant to which either Party or its Affiliates grants a license, sells or otherwise grants or transfers, including by option, to any Third Party (other than in connection with (i) a Change of Control, or (ii) a subcontract as permitted pursuant to Section 3.4.5) rights in or to, including any rights to further Develop or Commercialize, one or more Collaboration Products under such Program.

1.267 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.268 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.269 "**Unlicensed Component**" means (a) any API of a Combination Product that is not an siRNA Directed to the Collaboration Target or (b) any API that is otherwise administered in a

Clinical Trial of a Collaboration Product (in accordance with the protocol for such Clinical Trial) that is not an siRNA Directed to the Target.

1.270 "**Upfront Payment**" has the meaning set forth in Section 6.1.

1.271 "**Validated**" has the meaning set forth in the definition of "Regeneron Novel Liver Target."

1.272 [***].

1.273 "**Withholding**" has the meaning set forth in Section 6.8.

1.274 "**Withholding Action**" has the meaning set forth in Section 6.8.

ARTICLE 2
COLLABORATION MANAGEMENT

2.1 Joint Steering Committee.

2.1.1 Formation. Within fifteen (15) Business Days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"). The JSC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JSC on written notice to the other Party. Each Party shall appoint one of its representatives to serve as a co-chairperson of the JSC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party.

2.1.2 Specific Responsibilities. The JSC shall oversee the conduct of the Programs hereunder, including the Development and Manufacture of the Collaboration Products in the Territory under each Program. In particular, the JSC shall:

(a) review, discuss and coordinate the Parties' activities under this Agreement, including resolving any disputes that arise as set forth in this Agreement;

(b) review and discuss the nomination and selection of proposed Targets as new Collaboration Targets in accordance with Section 3.2.3;

(c) review and discuss whether any Target has a Therapeutic Rationale for NASH;

(d) review and discuss whether a [***] or other delivery technology is a [***] Delivery Technology, Other Delivery Technology, Non-CNS/Eye Delivery Technology or Non-Liver Delivery Technology, as applicable;

(e) [***]

(f) on a Program-by-Program basis, review, discuss and approve the Lead Candidate Criteria, and any amendments to the Lead Candidate Criteria, for a given Program;

(g) on a Program-by-Program basis, review, discuss and determine whether a Collaboration Product satisfies the Lead Candidate Criteria for such Program;

(h) on a Program-by-Program basis, select one or more Collaboration Products to be designated as Lead Candidates under such Program based on satisfaction of the Lead Candidate Criteria for such Program;

(i) on a Program-by-Program basis, review, discuss and approve the initial Candidate Discovery Plan (and any updates or material amendments thereto), in each case that has been submitted by the Parties in accordance with Section 3.4.1;

(j) serve as a forum for discussing the Development activities under each Candidate Discovery Plan;

(k) discuss any decision with respect to a Collaboration Product that either Party reasonably anticipates would give rise to a material obligation to a Third Party, including by requiring entry into an In-License with such Third Party;

(l) review, discuss and approve entering into any Third Party Transaction;

(m) determine to discontinue a given Program as set forth in Section 3.4.1(f);

(n) review, discuss and approve entering into any Product-Specific In-Licenses and discuss potential Core Technology In-Licenses, in each case, pursuant to Section 5.5.1;

(o) discuss whether to accept a Core Technology In-License as an In-License;

(p) [***]

(q) review and discuss any Eye Delivery Technology Development Plan and CNS Delivery Technology Development Plan (and any material updates or amendments thereto); and

(r) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.2 General Provisions Applicable to the JSC.

2.2.1 Meetings. The JSC shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once each Calendar Quarter during the Term, commencing from and after the time the JSC is established as provided herein unless the co-chairpersons agree otherwise. All JSC meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons; provided, that the JSC shall meet in person at least twice each Calendar Year, unless otherwise agreed by the Parties. Unless otherwise agreed by the Parties, all in-person meetings of the JSC shall be held on an alternating basis between Regeneron's facilities and Alnylam's facilities. A reasonable number of other representatives of a Party may attend any JSC meeting as non-voting observers (provided, that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in ARTICLE 8). Each Party shall be responsible for all of its own expenses of participating in the JSC. Either Party's representatives on the JSC may call a special meeting of the JSC upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.

2.2.2 Procedural Rules. The JSC shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. The JSC shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative appointed by each Party.

2.2.3 Dispute Resolution.

(a) JSC Disputes. If the JSC, after a period of thirty (30) days from the date a matter is submitted to it for decision (including if the JSC is unable to agree on any Candidate Discovery Plan or amendment thereto), is unable to make a decision due to a lack of required unanimity, either Party may require that the dispute be submitted to the Executive Officers for resolution by providing written notice to the other Party formally requesting that the dispute be resolved by the Executive Officers and specifying the nature of the dispute. If a dispute is referred

to the Executive Officers, then the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within fifteen (15) Business Days after receiving written notification of such dispute or such longer period of time as the Executive Officers may agree in writing. Any final decision mutually agreed to by the Executive Officers with respect to a dispute and set forth in writing shall be conclusive and binding on the Parties. If the Executive Officers cannot resolve such dispute within such fifteen (15) Business Days or such other period as agreed by the Executive Officers, such dispute will be resolved as follows:

(i) for any JSC Dispute other than a (A) Deadlocked Dispute, (B) Legal Dispute, or (C) Expert Dispute, such dispute shall be resolved by the Lead Party and the Lead Party's determination shall be binding on the Parties; provided that any final determination permitted to be made by the Lead Party under this Section 2.2.3(a)(i) shall: (X) be consistent with the terms of this Agreement, (Y) [***] (provided that, in the event that there is a dispute with respect to this clause (2), following escalation pursuant to Section 2.2.3(a), such matter shall be an "Expert Dispute" and resolved by the Expert in accordance with **Schedule 1**);

(ii) if the dispute is related to entering into (or the material terms of) any proposed [***] (each a "**Deadlocked Dispute**"), neither Party shall have the right to resolve such Deadlocked Dispute and such Deadlocked Dispute shall remain deadlocked until resolved by mutual agreement of the Parties;

(iii) if the dispute is related to a Legal Dispute, such dispute shall be resolved pursuant to Section 12.5; and

(iv) If the dispute is related to (a) the Lead Candidate Criteria (or any amendment to the Lead Candidate Criteria) in each case with respect to Liver Programs or CNS Programs (but excluding, for clarity, Eye Programs), (b) the determination as to whether a given Collaboration Product meets the Lead Candidate Criteria for a given Liver Program, CNS Program or Eye Program, (c) whether a proposed Target nominated by Regeneron in accordance with Section 3.2.2(a) is a NASH Target, (d) whether a proposed Target nominated by Regeneron in accordance with Section 3.2.3(b) is a Regeneron Novel Liver Target, or (e) whether a [***] or other delivery technology proposed under Section 3.2.3(e) is a type of [***] Delivery Technology, Other Delivery Technology, Non-CNS/Eye Delivery Technology or Non-Liver Delivery Technology (each of clauses (a)-(g), an "**Expert Dispute**"), the Parties will mutually agree on an Expert and will submit such matter for resolution by such Expert in accordance with **Schedule 1**, and the determination of the Expert will be binding on the Parties. For avoidance of doubt, the Parties shall be bound by the determination of such Expert and the JSC shall have no authority to modify or amend the finding of the Expert.

2.2.4 Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JSC shall not have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 12.7 or compliance with which may only be waived as provided in Section 12.10. For clarity, (a) the JSC shall serve as a discussion forum only for Core Technology In-Licenses, and the JSC shall not have any decision-making authority with respect thereto (and for clarity, each Party shall have decision-making authority with respect to its respective Core Technology In-Licenses), (b) the JSC shall serve as a discussion forum for research activities for ASO Reagents, [***] and (c) the JSC shall serve as a discussion forum for any CNS Delivery Technology Development Plan or Eye Delivery Technology Development Plan, and the JSC shall not have any decision-making authority with respect thereto.

2.3 Sub-Committees and Working Groups. The JSC may establish sub-committees or working groups to interact on a more frequent basis on specific projects and tasks assigned to them by the JSC; provided, that the authority of such sub-committees or working groups shall not expand beyond the authority of the JSC. Any such sub-committees or working groups shall have no decision-making authority, but shall make recommendations to the JSC for its review and approval.

2.4 Discontinuation of Participation on the JSC. The JSC shall continue to exist until the Parties mutually agreeing to disband the JSC. If the Parties mutually agree to disband the JSC, then all other subcommittees shall be immediately disbanded and shall have no further rights or obligations under this Agreement, and the Lead Party shall, except as otherwise provided in this Agreement, have the right to solely decide, without consultation with the Participating Party, all matters that are subject to the review or approval by the JSC or any subcommittee hereunder other than a Deadlocked Dispute, Legal Dispute or Expert Dispute, which each shall be resolved pursuant to Section 2.2.3(a) (*mutatis mutandis*).

2.5 Alliance Manager. Each Party shall appoint a senior representative who possesses a general understanding of this Agreement and pharmaceutical research, clinical, regulatory, manufacturing and commercialization matters and who shall oversee contact between the Parties for all matters between meetings of the JSC and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

2.6 License Agreements and Co-Co Collaboration Agreements. On a Program-by-Program basis, upon execution of a License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program, such Program (including the Collaboration Target and Collaboration

Products thereunder) and matters related thereto shall no longer continue to be within the purview of the JSC hereunder, and instead shall be within the purview of the Joint Steering Committee or any other Joint Committee (as defined in the License Agreement or Co-Co Collaboration Agreement) under the License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program.

ARTICLE 3
DEVELOPMENT AND REGULATORY

3.1 Overview.

3.1.1 Pursuant to the terms of this Agreement and as further provided in this ARTICLE 3, with respect to each Program, the Parties shall conduct Development of Collaboration Products Directed to the applicable Collaboration Target pursuant to such Program hereunder. Following designation of a Lead Candidate from the applicable Program, unless the Program is designated as a Terminated Program, the Parties shall enter into a License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program (including the Collaboration Target and Collaboration Products thereunder) as set forth in ARTICLE 4 to continue the further Development, Manufacture and Commercialization of Collaboration Products Directed to such Collaboration Target.

3.1.2 In furtherance of the collaboration hereunder, it is the intent of the Parties that Alnylam shall continue to further develop and optimize [***] and other delivery technologies for siRNAs Directed to Eye Targets and CNS Targets. Without limiting the foregoing,

(a) in the event that [***] then, [***] within thirty (30) days thereafter, Alnylam shall provide to the JSC for its review and discussion a written plan of activities that Alnylam proposes to conduct to develop [***] and other delivery technologies for siRNAs Directed to CNS Targets, and Alnylam shall consider in good faith any comments of Regeneron to such plan (the "**CNS Delivery Technology Development Plan**"), which CNS Delivery Technology Development Plan may be updated or amended by Alnylam from time to time following discussion of such update or amendment with Regeneron and consideration in good faith of any comments of Regeneron with respect thereto. Thereafter, Alnylam shall, at its sole cost, perform the activities set forth in the CNS Delivery Technology Development Plan; and

(b) in the event that [***], then, [***] within thirty (30) days thereafter, Alnylam shall provide to the JSC for its review and discussion a written plan of activities that Alnylam proposes to conduct to develop targeting ligands and other delivery technologies for siRNAs Directed to Eye Targets, and Alnylam shall consider in good faith any comments of Regeneron to such plan (the "**Eye Delivery Technology Development Plan**"), which Eye Delivery Technology Development Plan may be updated or amended by Alnylam from time to time following discussion of such update or amendment with Regeneron and consideration in good faith of any

comments of Regeneron with respect thereto. Thereafter, Alnylam shall, at its sole cost, perform the activities set forth in the Eye Delivery Technology Development Plan.

3.2 Collaboration Targets; Commencement of Programs.

3.2.1 Initial Collaboration Targets and Programs. The Parties agree and acknowledge that the Targets listed on **Schedule 3.2.1** are the potential initial Collaboration Targets from which the Parties shall mutually select (a) three (3) Targets within thirty (30) days after the Effective Date and (b) an additional three (3) such Targets within ninety (90) days after the Effective Date, in each case, for which Programs will commence during Calendar Year 2019 (each, an "**Initial Collaboration Target**"), and the Parties shall commence [***].

3.2.2 Reserved NASH Targets; Pre-Cleared Targets.

(a) From time to time during the Research Term, Regeneron shall have the right to add additional NASH Targets as a "Reserved NASH Target," or replace an existing Reserved NASH Target with an alternative NASH Target as a "Reserved NASH Target", in each case in accordance with this Section 3.2.2(a). In the event that Regeneron desires to add a given NASH Target as a Reserved NASH Target, or replace a given Reserved NASH Target with an alternative NASH Target as a Reserved NASH Target, then Regeneron shall propose in writing to Alnylam that such Target be added as a Reserved NASH Target. Upon receipt of such notice by Alnylam, the list of Reserved NASH Targets shall automatically be deemed to be updated to include such new Target as a "Reserved NASH Target" if such Target satisfies the requirements of the definition of "NASH Target," (provided that if the Parties fail to agree whether such Target satisfies the requirements of the definition of "NASH Target," such matter shall be an "Expert Dispute" and resolved by the Expert in accordance with **Schedule 1**) and, if applicable, to remove any replaced NASH Target (as determined by Regeneron in its sole discretion), unless at the time of receipt of such notice from Regeneron, [***], in which case the Reserved NASH Target list shall not be updated to include such Target (provided that [***]). If Alnylam disagrees that a Target proposed by Regeneron pursuant to this Section 3.2.2(a) is a NASH Target, then Alnylam shall notify Regeneron thereof in writing within ten (10) Business Days after receipt of such proposal from Regeneron, and such dispute shall be submitted for resolution by an Expert in accordance with the process set forth in Section 2.2.3(a)(iv). Notwithstanding anything herein to the contrary, there shall be no more than [***] Reserved NASH Targets at any time.

(b) From time to time during the Research Term, Regeneron shall have the right to [***]. In the event that Regeneron desires to add a given Target as a Pre-Cleared Target, Regeneron may provide the identity of such Target to Alnylam's independent Third Party gatekeeper for clearance by such Third Party gatekeeper in accordance with the gatekeeper process set forth in Section 3.2.3(a). Following completion of the Third Party gatekeeper process, Regeneron may,

in its sole discretion, provide written notice to Alnylam with the identity of such Target (provided that such notice shall not include any Target that Alnylam's Third Party gatekeeper identified as being prohibited (i.e., a "no") from being included as a Pre-Cleared Target hereunder pursuant to Section 3.2.3(a)) to become a Pre-Cleared Target hereunder. Alnylam shall provide written notice to Regeneron within fifteen (15) Business Days of the date of delivery of such notice to Alnylam whether there are [***]. In the event that Alnylam provides such written notice to Regeneron, then Regeneron may, in its sole discretion, determine not to include such Target as a Pre-Cleared Target. In the event that Regeneron elects to add a given Target as a Pre-Cleared Target in accordance with this Section 3.2.2(b), then **Schedule 1.197** shall automatically be deemed to include such Target as a Pre-Cleared Target.

3.2.3 Selection of New Collaboration Targets.

(a) Gatekeeper Process. Either (i) in connection with Regeneron's nomination of additional Pre-Cleared Targets in accordance with Section 3.2.2(b), or (ii) in preparation for the target selection process for new Collaboration Targets for a given Calendar Year during the Research Term, Regeneron may provide a list of Targets to Alnylam's independent Third Party gatekeeper for clearance by such Third Party gatekeeper; provided that for the target selection process for new Collaboration Targets for a given Calendar Year during the Research Term, (A) such list shall not include more [***] for such Calendar Year; and (B) if any of the Targets submitted by Regeneron to the Third Party gatekeeper are designated as a "no" or "encumbered", Regeneron may thereafter submit a reasonable number of additional Targets [***] for such Calendar Year to such Third Party gatekeeper for clearance. The Third Party gatekeeper shall confirm the availability of such Targets in accordance with Alnylam's independent Third Party gatekeeping processes, which processes will be agreed to by the Parties and established within sixty (60) days after the Effective Date (provided that such agreed Third Party gatekeeping process shall comply with the Existing Alnylam Third Party Agreements). Such Third Party gatekeeper shall provide written notice to Regeneron of the existence of any conflict that would prohibit or limit inclusion of the applicable Target as a Pre-Cleared Target or Collaboration Target hereunder (on a "yes" or "no" or "encumbered" basis, if any, where "yes" means that the Target is not restricted in any way, "no" means the Target is prohibited from being added as a Pre-Cleared Target or Collaboration Target and "encumbered" means that the Target may be added as a Pre-Cleared Target or Collaboration Target, but a Third Party has certain rights to such Target, and in the event that the Target is designated as "encumbered" the Third Party gatekeeper shall describe the encumbrances to Regeneron in writing) solely as a result of, and in accordance with, those provisions of the applicable Existing Alnylam Third Party Agreements (as such provisions are expressly set forth on **Schedule 9.2.15**), which conflict notification will be provided to Regeneron within fifteen (15) Business Days of the date of delivery of Regeneron's list to the Third Party gatekeeper. In the event that the Third Party gatekeeper reasonably determines that any Target on Regeneron's list has such a conflict (i.e., either a "no" or "encumbrance") and consequently may not be included (or may only be included subject

to the described encumbrances) as a Pre-Cleared Target or Collaboration Target under this Agreement, the Co-Co Collaboration Agreement or the License Agreement, then Regeneron may, in its discretion, select a reasonable number of alternative Targets (that are either a CNS Target, Liver Target or Eye Target) in replacement of such rejected (or encumbered) Target and notify the Third Party gatekeeper thereof in writing with an update to Regeneron's list of proposed Targets; provided that such replacement Targets shall again be subject to this Section 3.2.3(a). Alnylam shall notify the Third Party gatekeeper and Regeneron if any of the applicable provisions of the applicable Existing Alnylam Third Party Agreements (as such provisions are expressly set forth on **Schedule 9.2.15**) are no longer in force or effect. In the event that the Third Party gatekeeper had previously determined that any Target on Regeneron's list had such a conflict and consequently could not be included (or could only be included with encumbrances, as applicable) as a Pre-Cleared Target or Collaboration Target under this Agreement, the Third Party gatekeeper shall promptly notify Regeneron in writing if such conflict (or encumbrance, as applicable) no longer exists. Notwithstanding the foregoing, this Section 3.2.3(a) shall not apply to any Target that is a Pre-Cleared Target as of the Execution Date, a Reserved Liver Target or a Reserved NASH Target.

(b) Annual Collaboration Target List and Collaboration Target Selection. During the fourth quarter of Calendar Year 2019 and during the fourth quarter of each Calendar Year thereafter during the Research Term, [***] such list shall not include any such Targets that Alnylam's Third Party gatekeeper identified as being prohibited (i.e., a "no") from being included as a Collaboration Target hereunder pursuant to Section 3.2.3(a)) to become Collaboration Targets in the next Calendar Year (each, an "**Annual Collaboration Target List**"), subject to the following:

(i) [***] may not select more than the Annual Target Maximum number of Targets for a given Calendar Year.

(ii) For the target selection processes occurring [***], the new Collaboration Targets shall include at least [***] CNS Targets and [***] Eye Targets (unless otherwise mutually agreed by the Parties); provided that [***] may decrease such numbers of CNS Targets or Eye Targets if it has a good faith scientific reason to modify the number of new Collaboration Targets to less than [***] CNS Targets or Eye Targets, as applicable, based on data generated by or on behalf of the Parties under this Agreement or any Co-Co Collaboration Agreement or License Agreement.

(iii) Alnylam shall provide written notice to Regeneron within fifteen (15) Business Days of the date of delivery of such list to Alnylam whether there are any Alnylam-Initiated GLP Tox Permitted Competing Products or Alnylam-Partnered Permitted Competing Products Directed to any of the Targets as permitted pursuant to the exceptions to exclusivity set forth in Section 5.7.1(a)(D), or a program for Competing Products Directed to any

of the Targets as permitted pursuant to the exceptions to exclusivity set forth in Section 5.7.1(a)(B) or 5.7.1(a)(C), in each case, as of the date of Regeneron's nomination of such Target, as if such Target were a Collaboration Target hereunder. In the event that Alnylam provides such written notice to Regeneron, then Regeneron may, in its sole discretion, select an alternative Target (that is either a CNS Target, Liver Target or Eye Target) in replacement of such Target; provided that such alternative Target shall again be subject to this Section 3.2.3(b).

(iv) If Regeneron selects and lists a Liver Target that is not a Reserved Liver Target, Reserved NASH Target or Regeneron Novel Liver Target, then Alnylam shall have the right, within thirty (30) days after Regeneron proposes such Liver Target in its written list, to object to such Liver Target, in Alnylam's sole discretion, in which case such Liver Target shall not become a Collaboration Target for the next Calendar Year, and Regeneron may select an alternative Target (that is either a CNS Target, Liver Target or Eye Target) in replacement of such rejected Liver Target and notify Alnylam thereof in writing with an update to Regeneron's list of Collaboration Targets; provided that if such replacement Target is a Liver Target, such replacement Target shall again be subject to this Section 3.2.3(b)(iv).

(v) If Alnylam desires to select a Target other than the Targets proposed by Regeneron to become Collaboration Targets for the next Calendar Year, then Alnylam may propose up to [***] alternative Targets (provided that for the target selection processes occurring [***] one such Target must be a CNS Target, unless otherwise agreed to by Regeneron in writing) in writing to Regeneron within fifteen (15) Business Days after receipt of the list of Targets from Regeneron under this Section 3.2.3(b) (provided that any such Target proposed by Alnylam must be either a Liver Target or CNS Target).

(A) For any Calendar Year, if Regeneron agrees with a given Target proposed by Alnylam, then [***] will determine [***] which Target from the list proposed by Regeneron as Collaboration Targets for the next Calendar Year will be replaced by such Target selected by Alnylam, and such final list of Targets shall be the Collaboration Targets for the next Calendar Year (provided that, for clarity, any such replaced Target shall not be a "Declined Target").

(B) For any of the Targets proposed by Alnylam under this Section 3.2.3(b)(v) during the Target selection process in the fourth quarter of each of Calendar Years 2019, 2020 and 2021, the following shall apply: [***].

(C) For any of the Targets proposed by Alnylam under this Section 3.2.3(b)(v) during the target selection process [***], the following shall apply: If [***] shall be deemed to be a "Declined Target" for purposes of this Agreement.

(D) For any Declined Target, [***].

(vi) Upon either Party's request, the JSC shall convene an ad hoc meeting to discuss [***] Targets in accordance with Section 2.1.2(b).

(vii) If (1) Alnylam does not agree that a Target (other than a Reserved NASH Target) proposed by Regeneron satisfies the NASH Target definition, or (2) Alnylam does not agree that a Target proposed by Regeneron satisfies the definition of Regeneron Novel Liver Target, then, [***].

(viii) If a given nominated Target could fall within more than one category of Target (i.e., CNS Target, Eye Target or Liver Target), then the nominating Party will identify which category such Target will fall into for purposes of this Agreement (and any License Agreement or Co-Co Collaboration Agreement), as applicable, when such Target is nominated in accordance with this Section 3.2.3(b).

(c) Within twenty (20) days after the final list of Collaboration Targets for the next Calendar Year is determined pursuant to Section 3.2.3(b), (i) Alnylam shall provide to Regeneron a written list of (1) any additional Patent Rights Controlled by Alnylam (or its Affiliates) to be included within the "Alnylam Core Technology Patents" or the "Alnylam Product-Specific Patents", as applicable, provided that, with respect to "Alnylam Core Technology Patents" only to the extent not previously listed on **Schedule 1.16,** and (2) any then existing Product-Related In-Licenses (to be set forth on Part 2 of **Schedule 1.108**) between Alnylam (or its Affiliates) and a Third Party in effect as of the date that the Target becomes a Collaboration Target hereunder, which shall thereafter be an "Existing Alnylam In-License" (and shall also provide to Regeneron a true, correct and complete copy of such agreements, subject to redaction as Alnylam's outside counsel determines appropriate to comply with confidentiality obligations); in each case, with respect to such Collaboration Target, and (ii) Regeneron shall provide to Alnylam a written list of (1) any additional Patent Rights Controlled by Regeneron (or its Affiliates) to be included within the "Regeneron Product-Specific Patents", and (2) any then existing Product-Related In-Licenses (to be set forth on Part 2 of **Schedule 1.111**) between Regeneron (or its Affiliates) and a Third Party in effect as of the date that the Target becomes a Collaboration Target hereunder, which shall thereafter be an "Existing Regeneron In-License" (and shall also provide to Alnylam a true, correct and complete copy of such agreements, subject to redaction as Regeneron's outside counsel determines appropriate to comply with confidentiality obligations); in each case, with respect to such Collaboration Target.

(d) At any time during the Research Term, but no more than [***], either Party may propose in writing to the other Party that a Target that is not already a Collaboration Target or Reserved NASH Target hereunder is or is not a NASH Target, as applicable; provided that Alnylam may only propose Targets pursuant to this Section 3.2.3(d) for which Alnylam has a good faith intention (itself or together with a Third Party) to commence an siRNA research program

for such Target within the next twelve (12) months. Within thirty (30) days of receiving such request, the non-requesting Party may agree or object. Upon any such objection, the proposing Party, if it so elects, may elect to invoke the dispute resolution process set forth in Section 3.2.3(b)(vii) to make such determination. Upon any agreement by the Parties or resolution by the dispute resolution process set forth in Section 3.2.3(b)(vii), the JSC will record the applicable classification of the Target in its minutes; provided that, for clarity, either Party shall have the right to subsequently dispute the determination made pursuant to this Section 3.2.3(d) if new information becomes available with respect to such Target, and if a new determination is made, the JSC minutes will be updated to reflect such new determination.

(e) At any time during the Term, either Party may propose in writing to the other Party that [***] or other delivery technology is or is not a type of [***] Delivery Technology, Other Delivery Technology, Non-CNS/Eye Delivery Technology or Non-Liver Delivery Technology, as measured by [***]. Within thirty (30) days of receiving such request, together with reasonable supporting data from the requesting Party, if any, the non-requesting Party may agree or object. Upon any such objection, the proposing Party, if it so elects, may elect to invoke the dispute resolution process set forth in Section 3.2.3(b)(vii) to determine if a targeting ligand or other delivery technology is or is not a type of [***] Delivery Technology, Other Delivery Technology, Non-CNS/Eye Delivery Technology or Non-Liver Delivery Technology. Upon any agreement by the Parties or resolution by the dispute resolution process set forth in Section 3.2.3(b)(vii), the JSC will record the applicable classification of the [***] or other delivery technology in its minutes; provided that, for clarity, either Party shall have the right to subsequently dispute the determination made pursuant to this Section 3.2.3(e) if new information becomes available with respect to such [***] or other delivery technology (other than GalNAc, which shall remain classified as Non-CNS/Eye Delivery Technology in all cases), and if a new determination is made, the JSC minutes will be updated to reflect such new determination.

3.2.4 Commencement of Programs.

(a) For each Target selected pursuant to Section 3.2.3(b) to be a new Collaboration Target for a given Calendar Year, the Parties will initiate new Programs hereunder for each such Collaboration Target during such Calendar Year (provided that for Calendar Year 2019, the Parties shall initiate each of the Initial Programs as set forth in Section 3.2.1), and the Parties shall prepare, in accordance with Section 3.4.1, the initial Candidate Discovery Plan for each such new Program.

(b) With respect to each Target that is added as a new "Collaboration Target" pursuant to Section 3.2.3(b), (i) the Program for such new Collaboration Target shall be a "**New Program**" hereunder, (ii) the Patent Rights designated as "Alnylam Core Technology Patents" or "Alnylam Product-Specific Patents", respectively, pursuant to Section 3.2.3(c) shall be part of

the “Alnylam Core Technology Patents” or “Alnylam Product-Specific Patents”, respectively, for such New Program, (iii) the Patent Rights designated as “Regeneron Product-Specific Patents” pursuant to Section 3.2.3(c) shall be part of the Regeneron Product-Specific Patents for such New Program, (iv) the agreements designated as “Existing Alnylam In-Licenses” pursuant to Section 3.2.3(c) shall be “Existing Alnylam In-Licenses” for such New Program, and (v) the agreements designated as “Existing Regeneron In-Licenses” pursuant to Section 3.2.3(c) shall be “Existing Regeneron In-Licenses” for such New Program.

3.3 Research Term; Research Term Extension; Research Term Tail; Discontinuance of Programs.

3.3.1 Research Term. The Parties agree and acknowledge that new Collaboration Targets will only be chosen during the Research Term; provided that, for the avoidance of doubt, if a given Collaboration Target was chosen during the Research Term, then the Program for such Collaboration Target shall continue hereunder following the Research Term during the Research Term Tail (even if activities under such Program were not commenced during the Research Term), subject to Section 3.3.3.

3.3.2 Research Term Extension by Regeneron. Regeneron shall have the right, in its sole discretion, to extend the Research Term for the Research Term Extension Period (the “**Research Extension Option**”) by providing Alnylam with written notice of such election no later than [***] and thereafter paying Alnylam the Research Extension Fee within sixty (60) days after delivery of such notice.

3.3.3 Research Term Tail.

(a) The Parties shall conduct, or continue to conduct, as applicable, Development activities under each Program for any Collaboration Targets that were chosen as of the end of the Research Term (even if activities under such Program were not commenced during the Research Term) through the end of the Research Term Tail for the applicable Program in accordance with this Agreement, with the goal of identifying Lead Candidates under each such Program prior to the end of the Research Term Tail. For clarity, during the Research Term Tail for a given Program, Alnylam and its Affiliates shall have no obligation to initiate the synthesis of a Collaboration Product under such Program if [***].

(b) With respect to any Program for [***] then within thirty (30) days after the end of the Research Term Tail, each Party shall deliver to the other Party its Program Data Package for such [***] (provided that, with respect to any Eye Program, Regeneron’s Program Data Package delivered to Alnylam shall only include the information contained in parts (c) and (d) of the definition of “Program Data Package”). For each [***] that is an Eye Program, Regeneron shall have the right, in its sole discretion, to elect to enter into a License Agreement for such Eye Program

with Regeneron as the “Licensee” thereunder (which election may be made by Regeneron on a [***] basis), by providing written notice of such election to Alnylam within [***] days after receipt of the applicable Program Data Packages (the “**Research Term Tail Election Period**”). If Regeneron makes its election to enter into a License Agreement for any such Eye Program during the Research Term Tail Election Period for the applicable Program, then the Parties, subject to Section 4.9, shall enter into a License Agreement with respect to such Eye Program (and the Collaboration Target and Collaboration Products thereunder), including completing the exhibits and schedules thereto, with Regeneron as the “Licensee” under such License Agreement (and, subject to Section 4.9, pending such time as the License Agreement is entered into for such Program, Alnylam shall, and hereby does, grant to Regeneron the licenses as set forth in the License Agreement with respect to such Eye Program (including the Collaboration Target and Collaboration Products thereunder)). For the avoidance of doubt, the provisions of Sections 4.5 and 4.7 shall apply with respect to any such License Agreement. For each [***] that is a CNS Program or Liver Program, the Parties shall have the right, on an alternating basis (with Regeneron having the first right to pick any such [***] for which to enter into a License Agreement as the “Licensee”, and Alnylam having the second right to pick any such [***] for which to enter into a License Agreement as the “Licensee”, and so on, provided that if either Regeneron or Alnylam, as applicable, does not choose to pick any of the remaining [***] for which to enter into a License Agreement as the “Licensee” on one of its turns, then the other Party shall have thereafter have the sole right to pick any one or more of the remaining [***] that are CNS Programs or Liver Programs for which to enter into a License Agreement as the “Licensee”), to elect to enter into a License Agreement for such [***] with such Party as the “Licensee” thereunder by providing written notice of such election to the other Party during the Research Term Tail Election Period and complying with the terms and conditions of this Section 3.3.3(b) (*mutatis mutandis*); provided that, solely with respect to those [***] for which the Parties enter into a License Agreement with Alnylam as the “Licensee”, Regeneron shall pay to Alnylam the Lead Candidate Payment for each such [***] within thirty (30) days after the date that the first Lead Candidate is designated (consistent with the Lead Candidate Criteria set forth in the applicable Candidate Discovery Plan prior to the termination of such Candidate Discovery Plan) under such [***] under such License Agreement and the JSC (under the applicable License Agreement) is notified of such designation (and, for clarity, with respect to any [***] for which the Parties entered into a License Agreement with Regeneron as the “Licensee”, Regeneron shall not be required to make any Lead Candidate Payments). If a Party does not make its election to enter into the License Agreement for a given Program during the Research Term Tail Election Period as set forth in this Section 3.3.3(b), then such Program shall be deemed to be a “Terminated Program” and the Collaboration Target under such Terminated Program, a “Terminated Target”.

3.4 Development Activities.

3.4.1 Candidate Discovery Activities.

(a) With respect to the Initial Collaboration Targets, (i) no later than sixty (60) days after the Effective Date, for at least [***] such Initial Collaboration Targets and (ii) promptly thereafter for the remaining Initial Collaboration Targets, the Parties shall prepare and provide the JSC with a proposed Candidate Discovery Plan (including the Lead Candidate Criteria) for each such Initial Collaboration Target for the JSC's review, discussion and approval.

(b) With respect to each Collaboration Target (other than the Initial Collaboration Targets), within thirty (30) days after the beginning of the Calendar Year for which such Target was added as a new Collaboration Target hereunder, the Parties shall prepare and provide the JSC with a proposed Candidate Discovery Plan (including the Lead Candidate Criteria) for each such new Collaboration Target for the JSC's review, discussion and approval.

(c) During the preparation of the Candidate Discovery Plan for a given Collaboration Target that is a CNS Target or an Eye Target, the Parties shall discuss the inclusion of the research of [***].

(d) The JSC shall endeavor to approve the Candidate Discovery Plan within thirty (30) days after receipt of the proposed Candidate Discovery Plan; provided, that the Candidate Discovery Plan shall not become effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.2.3(a) or the Lead Party pursuant to Section 2.2.3(a)(i)); provided further that the Lead Candidate Criteria must be approved by the JSC by consensus or the Executive Officers or the Expert (or, with respect to an Eye Program, the Lead Party pursuant to Section 2.2.3(a) (i.e., without the Lead Party exercising its final decision-making authority, other than with respect to an Eye Program)). Following approval of the Candidate Discovery Plan for a given Program, the JSC will review such Candidate Discovery Plan annually and discuss, propose and approve updates and material amendments thereto; provided that no update or material amendment to a given Candidate Discovery Plan shall be effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.2.3(a) or the Lead Party pursuant to Section 2.2.3(a)(i)).

(e) Each Party shall use Commercially Reasonable Efforts to (i) perform the Development activities assigned to it under the Candidate Discovery Plan in accordance with the timeline set forth therein and (ii) achieve the goals and objectives set forth in the Candidate Discovery Plan.

(f) Prior to designation of the first Lead Candidate from a given Program, if either Party determines in good faith that the Program for such Collaboration Target is not

reasonably likely to result in a Collaboration Product that satisfies the Lead Candidate Criteria for such Collaboration Target, then such Party shall notify the other Party through the JSC of such determination. In such case, the JSC (or the Executive Officers pursuant to Section 2.2.3(a) or the Lead Party pursuant to Section 2.2.3(a)(i)) may determine to discontinue such Program. In the event that the JSC (or the Executive Officers pursuant to Section 2.2.3(a) or the Lead Party pursuant to Section 2.2.3(a)(i)) determines to discontinue any such Program, then such Program shall be deemed to be a "Terminated Program" and the Collaboration Target under such a "Terminated Target", and the Parties shall promptly wind-down, in compliance with Applicable Law, all Development activities under such Program. In the event that one or more Programs become Terminated Programs during a given Calendar Year, then [***]. In addition, in the event that a given Program becomes a "Terminated Program" pursuant to this Section 3.4.1(f) as a result of Regeneron exercising its Lead Party decision-making right pursuant to Section 2.2.3(a)(i) after the first dosing of the first non-human primate with Collaboration Product in the pilot non-human primate study under such Program (but before a Lead Candidate is designated from such Program), then Regeneron shall pay to Alnylam the Lead Candidate Payment for such Program within thirty (30) days after such Program becomes a "Terminated Program" pursuant to this Section 3.4.1(f).

(g) As part of the activities under a given Program, in order to identify a Lead Candidate for such Program, Alnylam shall generate and Develop new siRNAs Directed to the Collaboration Target under such Program, and shall also contribute and Develop siRNAs Directed to the Collaboration Target under such Program that are otherwise controlled by Alnylam or its Affiliates (provided that, for clarity, [***]). Without limiting the foregoing, for a given Collaboration Target, in the event that [***].

(h) For a given Collaboration Target, in the event that [***].

3.4.2 Operational Discretion. Subject to the terms and conditions of this Agreement, the Party to which an activity under any Candidate Discovery Plan is assigned shall have the right to make operational decisions with respect to how such activity is conducted from an operational perspective; provided that (a) such decisions are consistent with this Agreement and the Candidate Discovery Plan and (b) such decisions are consistent with customary business practices for other of its similar products.

3.4.3 Continuation of Activities. For the avoidance of doubt, with respect to a given Program, if any activities under the Candidate Discovery Plan have not been completed prior to entering into a Co-Co Collaboration Agreement or License Agreement, as applicable, for such Program, then such activities shall continue to be conducted under a Co-Co Collaboration Agreement or License Agreement; provided that until such time as a Co-Co Collaboration Agreement or License Agreement is entered into, the Parties shall continue to perform the activities under the Candidate Discovery Plan hereunder even if a Lead Candidate has already been identified.

3.4.4 Assistance. For so long as a given Program is being conducted hereunder, promptly after request by a Party, the non-requesting Party shall (and shall cause its Affiliates to) cooperate with the requesting Party and provide reasonable assistance to the requesting Party to enable the requesting Party (and its Affiliates) to conduct its Development activities under such Program in accordance with the applicable Candidate Discovery Plan for such Program, as reasonably requested by the requesting Party, including providing the requesting Party (and its designees) with reasonable access by teleconference or in-person (as requested by the requesting Party) to then-employed personnel of the non-requesting Party (and personnel of its Affiliates) to assist with the transition and answer questions related to Collaboration Products or the Development thereof pursuant to this Agreement in accordance with the applicable Candidate Discovery Plan for such Program.

3.4.5 Subcontracting. Each Party shall have the right to subcontract any of its Development activities under this Agreement to a Third Party (a "**Third Party Provider**") without the other Party's consent (provided that Alnylam shall not subcontract any activities allocated to Alnylam under a Candidate Discovery Plan without Regeneron's prior consent, such consent not to be unreasonably withheld, conditioned or delayed, except that Alnylam may subcontract those activities set forth on **Schedule 3.4.5** to those Third Party Providers as set forth on such schedule to the extent Alnylam subcontracts such activities in the ordinary course of Alnylam's business, which schedule may be updated from time to time by the JSC to include additional Third Party Providers upon Alnylam's reasonable request and Regeneron's consent, not to be unreasonably withheld, conditioned or delayed); provided that any subcontract entered into by a Party pursuant to this Section 3.4.5 must (a) be in writing, (b) be consistent with the terms and conditions of this Agreement, including containing confidentiality provisions at least as protective as those contained in ARTICLE 8, and (c) provide the other Party with the same rights with respect to any intellectual property arising from the subcontracted activities as it would have if the subcontracting Party performed such activities under this Agreement (except that with respect to any subcontract entered into with a Third Party contract manufacturer, such Third Party may retain ownership of any general manufacturing process improvement of general application; provided that such Third Party grants the subcontracting Party a sublicenseable license with respect to any such improvement to the extent related to a Collaboration Product). In the event the subcontracting Party seeks to subcontract with an academic, governmental, not-for-profit or public institution and is unable to comply with subsection (c) above, then the subcontracting Party may submit a written request to the other Party for its consent to such subcontract through the Alliance Managers. If the other Party fails to respond to such request within three (3) weeks after receipt of such written request, such request shall be deemed to have been approved, and the subcontracting Party may proceed with the subcontract. The subcontracting Party shall (x) oversee the performance by its subcontractors of the activities subcontracted pursuant to this Section 3.4.5 in a manner that would be reasonably expected to result in their timely and successful completion and (y) be responsible and liable for the actions and

omissions of its subcontractors. No subcontracting pursuant to this Section 3.4.5 shall relieve the subcontracting Party of any of its obligations, or the other Party of any of its rights, under this Agreement.

3.4.6 Compliance. Each Party shall perform or cause to be performed any and all of its Development activities, including its activities under each applicable Candidate Discovery Plan, in a good scientific manner and in compliance with all Applicable Law.

3.5 [***]. Except as expressly set forth in [***].

3.6 Information Exchange. As long as a Party is conducting Development activities under this Agreement, including under a Candidate Discovery Plan, upon the reasonable request of such Party (the "**Requesting Party**"), the non-Requesting Party shall provide to the Requesting Party Information that is licensed to the other Party under this Agreement to the extent that it is necessary or reasonably useful for the Requesting Party to perform its Development activities under any Candidate Discovery Plan, or, with respect to the Lead Party as the Requesting Party, for Developing any Collaboration Product or for filing, obtaining or maintaining INDs or Regulatory Approval for any Collaboration Product, including copies of all material scientific information and data related to such Collaboration Product.

3.7 Records and Reports.

3.7.1 Each of Alnylam and Regeneron shall, and shall ensure that its Third Party Providers, maintain complete, current and accurate records of all of its Development activities under this Agreement, including under each Candidate Discovery Plan, and all data and other information resulting from such Development activities, which records shall (a) be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, (b) properly reflect all work done and results achieved in the performance of such Development activities, and (c) record only such Development activities and shall not include or be commingled with records of activities that are not conducted under this Agreement. On a Program-by-Program basis, Alnylam or Regeneron, as the case may be, shall retain, or cause to the retained, such records for at least three (3) years after the termination of this Agreement (in its entirety) or termination of the applicable Program, whichever is earlier, or for such longer period as may be required by Applicable Law.

3.7.2 For each given Program, each Party shall promptly provide to the JSC a summary of material non-clinical data with respect to any Development activities under each Candidate Discovery Plan for such Program, and, upon the reasonable request by the other Party, shall provide the other Party copies of or access to all non-clinical data, and other material Information, results, and analyses with respect to such Development activities for such Program (collectively, "**Development Data**"). In addition, upon the reasonable request of a Party, the other

Party shall provide to the requesting Party any material Development Data for such Program that has not been previously provided by such other Party to the JSC pursuant to this Section 3.7.2.

3.7.3 Notwithstanding anything to the contrary contained herein, neither Party shall be required to provide to, or otherwise share with, the other Party any data (including Development Data and CMC information) specific to such Party's Proprietary Unlicensed Component, unless otherwise required by a Regulatory Authority.

3.8 Material Transfer. In the event a Party transfers to the other Party any Materials under this Agreement, the receiving Party shall: (a) use such Materials solely for the purpose of exercising its rights or fulfilling its obligations under this Agreement (or under a License Agreement or Co-Co Collaboration Agreement, as applicable) and for no other purpose; and (b) not transfer such Materials to any Third Party without the providing Party's prior written consent, provided that the receiving Party shall have the right to transfer such Materials to its Sublicensees or subcontractors solely to the extent for such Third Party to conduct the activities on behalf of, or as a Sublicensee of, such receiving Party in furtherance of this Agreement (or a License Agreement or Co-Co Collaboration Agreement, as applicable). In the event the Parties anticipate the transfer of any patient samples or patient information, the Parties shall negotiate in good faith and enter into an agreement governing such transfer and subsequent use, in compliance with all Applicable Law.

ARTICLE 4
LICENSE AGREEMENTS AND CO-CO COLLABORATION AGREEMENTS

4.1 Delivery of Program Data Package. On a Program-by-Program basis, within thirty (30) days after a Party reasonably believes that one or more Collaboration Products satisfies the Lead Candidate Criteria and notifies the other Party thereof in writing, each Party shall provide to the other Party its Program Data Package for such Program (provided that, with respect to any Eye Program, Regeneron's Program Data Package delivered to Alnylam shall only include the information contained in parts (c) and (d) of the definition of "Program Data Package"). For purposes of this Agreement, the "**Data Package Delivery Date**" for a given Program shall be the date on which the applicable Program Data Packages are delivered for such Program pursuant to this Section 4.1 (or, if elected by a Party, such date as the other Party was supposed to deliver its Program Data Package for such Program pursuant to this Section 4.1, if such Program Data Package was not timely delivered by such other Party).

4.2 Selection of a Lead Candidate. On a Program-by-Program basis, within fifteen (15) Business Days after the Data Package Delivery Date for such Program, the JSC will meet and review such Program Data Packages for such Program. The JSC will determine whether any of the Collaboration Products for such Program satisfies the Lead Candidate Criteria, in which case the JSC shall designate such Collaboration Product(s) as a Lead Candidate for such Program (unless

otherwise mutually agreed by the Parties). If the JSC does not believe that any Collaboration Products for such Program satisfies the Lead Candidate Criteria, then the Parties shall continue to conduct additional Development activities with respect to such Program in accordance with the Candidate Discovery Plan (as may be amended in accordance with this Agreement), and thereafter resubmit Program Data Packages as and to the extent applicable in accordance with Section 4.1. In the event that the JSC does not agree on whether any Collaboration Product satisfies the Lead Candidate Criteria for a given Program, then such dispute will be resolved in accordance with Section 2.2.3(a)(iv). Notwithstanding the foregoing, the Parties may mutually agree (or, with respect to an Eye Program, Regeneron may determine) that a Collaboration Product for such Program will progress to IND-enabling studies even if such Collaboration Product does not otherwise satisfy the Lead Candidate Criteria, and, in such case, such Collaboration Product will be deemed to be a "Lead Candidate" for such Program. Any designation of a Collaboration Product as a Lead Candidate for a given Program by the JSC or by the Expert in accordance with Section 2.2.3(a)(iv), or by mutual agreement of the Parties (or, with respect to an Eye Program, by Regeneron) pursuant to the preceding sentence, shall be recorded in the minutes of the JSC, and the date on which such Lead Candidate is so designated by the JSC or the Expert or mutually by the Parties (as applicable) shall be the "**Lead Candidate Date**".

4.3 Eye Programs.

4.3.1 Lead Continuation Party. Regeneron shall be the Lead Continuation Party for each Eye Program (and Regeneron shall be deemed to be designated as the "Lead Continuation Party" for a given Eye Program as of the Lead Candidate Date for such Eye Program).

4.3.2 Regeneron License Agreements. Except as set forth in Section 5.7.1(a)(C)(b), on an Eye Program-by-Eye Program basis, within twenty (20) Business Days after designation of Regeneron as the Lead Continuation Party for a given Eye Program pursuant to Section 4.3.1, the Parties shall enter into a License Agreement with respect to such Eye Program (and the Collaboration Target and Collaboration Products thereunder), including completing the exhibits and schedules thereto, with Regeneron as the "Licensee" under such License Agreement. Notwithstanding the foregoing, if Regeneron, in its sole discretion, notifies Alnylam in writing within twenty (20) Business Days after such designation of Regeneron as the Lead Continuation Party for such Eye Program that Regeneron does not wish to enter into a License Agreement for such Eye Program with Regeneron as the "Licensee" thereunder (such notice for a given Eye Program, a "**Regeneron Eye Program Discontinuation Notice**"), then (a) the Parties shall not enter into such License Agreement for such Eye Program, (b) the Eye Program shall be deemed to be a "Terminated Program" (and not a Licensed Program) and (c) the Collaboration Target under such Eye Program shall be deemed to be a "Terminated Target". Unless Regeneron has provided a Regeneron Eye Program Discontinuation Notice for a given Eye Program, subject to Section 4.9, effective as of the Lead Candidate Date and pending such time as the License Agreement is entered

into for such Eye Program, Alnylam shall, and hereby does, grant to Regeneron the licenses as set forth in the License Agreement with respect to such Eye Program (including the Collaboration Target and Collaboration Products thereunder).

4.4 Liver Programs and CNS Programs.

4.4.1 Lead Continuation Party.

(a) With respect to Liver Programs, the designation of the Lead Continuation Party for each such Liver Program shall alternate between the Parties [***].

(b) With respect to CNS Programs, the designation of the Lead Continuation Party for each such CNS Program shall alternate between the Parties, [***].

(c) On a Liver Program-by-Liver Program or CNS Program-by-CNS Program basis, as applicable, within fifteen (15) Business Days after the Lead Continuation Party is designated for a given Program pursuant to Section 4.4.1(a) or 4.4.1(b), as applicable, such Lead Continuation Party shall deliver to the other Party a preliminary, non-binding development plan (the "**Preliminary Pre-Clinical Plan**") prepared in good faith by the Lead Continuation Party setting forth (i) the IND-enabling Development activities anticipated to be conducted for the Collaboration Products under such Program, (ii) the anticipated target product profile for the Collaboration Products under such Program, (iii) the initial indications for which such Lead Continuation Party anticipates developing the Collaboration Products under such Program, and (iv) any Combination Products for which such Lead Continuation Party anticipates developing under such Program.

4.4.2 Co-Co Collaboration Agreements. On a Liver Program-by-Liver Program or CNS Program-by-CNS Program basis, as applicable, no later than fifteen (15) Business Days after receipt of the plan for a given Liver Program or CNS Program, as applicable, pursuant to Section 4.4.1(c) (the "**Collaboration Election Period**"), the non-Lead Continuation Party shall have the right, by written notice to the Lead Continuation Party, to elect to make such Program a Co-Co Program and enter into a Co-Co Collaboration Agreement (a "**Collaboration Election Notice**") with the Lead Continuation Party as the "Lead Party" thereunder. If the non-Lead Continuation Party delivers the Collaboration Election Notice for a given Liver Program or CNS Program, as applicable, then (a) within twenty (20) Business Days thereafter, the Parties shall enter into a Co-Co Collaboration Agreement with respect to such Program (and the Collaboration Target and Collaboration Products thereunder), including completing the exhibits and schedules thereto, with the Lead Continuation Party as the "Lead Party" under such Co-Co Collaboration Agreement and (b) subject to Section 4.9, effective as of the date of the Collaboration Election Notice and pending such time as the Co-Co Collaboration Agreement is entered into for such Liver Program or CNS Program, as applicable, each Party shall, and hereby does, grant to the other Party the

licenses as set forth in the Co-Co Collaboration Agreement with respect to such Liver Program or CNS Program, as applicable (including the Collaboration Target and Collaboration Products thereunder). Notwithstanding the foregoing, if the non-Lead Continuation Party delivers the Collaboration Election Notice for a given Liver Program or CNS Program, as applicable, but the Lead Continuation Party, in its sole discretion, notifies the non-Lead Continuation Party in writing within ten (10) Business Days after receipt of the Collaboration Election Notice that such Lead Continuation Party does not wish to enter into a Co-Co Collaboration Agreement and be the "Lead Party" thereunder for such Liver Program or CNS Program, as applicable, then (a) the Parties shall not enter into such Co-Co Collaboration Agreement for such Liver Program or CNS Program (and the license in the foregoing clause (b) shall not apply), as applicable, and (b) the provisions of Section 4.4.3 shall apply for such Program. If the non-Lead Continuation Party does not deliver the Collaboration Election Notice for a given Liver Program or CNS Program, as applicable, then the provisions of Section 4.4.4 shall apply for such Program.

4.4.3 License Agreement for Non-Lead Continuation Party. On a Liver Program-by-Liver Program or CNS Program-by-CNS Program basis, as applicable, if the non-Lead Continuation Party delivers a Collaboration Election Notice for a given Liver Program or CNS Program, as applicable, pursuant to Section 4.4.2, but the Lead Continuation Party thereafter notifies the non-Lead Continuation Party in writing in accordance with Section 4.4.2 that it does not desire to enter into a Co-Co Collaboration Agreement for such Program, then within ten (10) Business Days after such notice from the Lead Continuation Party, the Parties shall enter into a License Agreement with respect to such Program (and the Collaboration Target and Collaboration Products thereunder), including completing the exhibits and schedules thereto, with the non-Lead Continuation Party as the "Licensee" under such License Agreement. Subject to Section 4.9, effective as of the date the Lead Continuation Party notifies the non-Lead Continuation Party in writing in accordance with Section 4.4.2 that it does not desire to enter into a Co-Co Collaboration Agreement for such Liver Program or CNS Program, as applicable, and pending such time as the License Agreement is entered into for such Liver Program or CNS Program, as applicable, the Lead Continuation Party shall, and hereby does, grant to the non-Lead Continuation Party the licenses as set forth in the License Agreement with respect to such Liver Program or CNS Program, as applicable (including the Collaboration Target and Collaboration Products thereunder). Notwithstanding the foregoing, if the non-Lead Continuation Party, in its sole discretion, notifies the other Party in writing within ten (10) Business Days after the non-Lead Continuation Party first has the right to enter into a License Agreement for such Program pursuant to this Section 4.4.3, that such non-Lead Continuation Party does not wish to enter into a License Agreement and be the "Licensee" thereunder for such Liver Program or CNS Program, as applicable, then (a) the Parties shall not enter into such License Agreement for such Liver Program or CNS Program, as applicable, with the non-Lead Continuation Party as the "Licensee" thereunder (and the license grant to such non-Lead Continuation Party set forth in this Section 4.4.3 shall not apply), and (b) (i) such Liver

Program or CNS Program, as applicable, shall be deemed to be a "Terminated Program" and (ii) the Collaboration Target under such Program shall be deemed to be a "Terminated Target".

4.4.4 License Agreement for Lead Continuation Party. On a Liver Program-by-Liver Program or CNS Program-by-CNS Program basis, as applicable, if the non-Lead Continuation Party does not deliver a Collaboration Election Notice for a given Liver Program or CNS Program, as applicable, pursuant to Section 4.4.2, then within twenty (20) Business Days after the end of the Collaboration Election Period for such Program, the Parties shall enter into a License Agreement with respect to such Program (and the Collaboration Target and Collaboration Products thereunder), including completing the exhibits and schedules thereto, with the Lead Continuation Party as the "Licensee" under such License Agreement. Subject to Section 4.9, effective as of the end of the Collaboration Election Period for a given Liver Program or CNS Program, as applicable, pursuant to Section 4.4.2, and pending such time as the License Agreement is entered into for such Liver Program or CNS Program, as applicable, the non-Lead Continuation Party shall, and hereby does, grant to the Lead Continuation Party the licenses as set forth in the License Agreement with respect to such Liver Program or CNS Program, as applicable (including the Collaboration Target and Collaboration Products thereunder). Notwithstanding the foregoing, if the Lead Continuation Party, in its sole discretion, notifies the other Party in writing within ten (10) Business Days after the end of the Collaboration Election Period for such Program, that such Lead Continuation Party does not wish to enter into a License Agreement and be the "Licensee" thereunder for such Liver Program or CNS Program, as applicable, then (a) the Parties shall not enter into such License Agreement for such Liver Program or CNS Program, as applicable, with the Lead Continuation Party as the "Licensee" thereunder (and the license grant to such Lead Continuation Party set forth in this Section 4.4.4 shall not apply), and (b) the non-Lead Continuation Party shall have the right, within thirty (30) days after such notice from the Lead Continuation Party, to notify the Lead Continuation Party that such non-Lead Continuation Party desires to enter into a License Agreement for such Program with the non-Lead Continuation Party as the "Licensee" thereunder, in which case the Parties shall enter into such License Agreement in accordance with the provisions of Section 4.4.3, provided that if the non-Lead Continuation Party does not deliver such notice then (i) such Liver Program or CNS Program, as applicable, shall be deemed to be a "Terminated Program" and (ii) the Collaboration Target under such Program shall be deemed to be a "Terminated Target".

4.5 Entering Into License Agreements and Co-Co Collaboration Agreements. The Parties agree and acknowledge that the form of License Agreement and Co-Co Collaboration Agreement are attached as exhibits to this Agreement. If the Parties are to enter into a License Agreement or Co-Co Collaboration Agreement, as applicable, with respect to a given Program pursuant to Section 4.3 or Section 4.4, as applicable, the Parties will execute such License Agreement or Co-Co Collaboration Agreement for the applicable Program (including the Collaboration Target and Collaboration Products thereunder), which shall consist of mechanically inserting the relevant schedules and exhibits, completing the applicable blank provisions, and deleting bracketed

provisions that are not applicable in the form of License Agreement or form of Co-Co Collaboration Agreement, in each case, in accordance with the footnotes in such form agreements to the extent applicable. For clarity, a License Agreement or Co-Co Collaboration Agreement, as applicable, with respect to a given Program will not contain any additional provisions, subject to Section 13.7.2 of the applicable Co-Co Collaboration Agreement or Section 13.7.2 of the applicable License Agreement.

4.6 No Encumbrances.

4.6.1 On a Program-by-Program basis, commencing on the date of selection of each Initial Collaboration Target in accordance with Section 3.2.1 (or for the period commencing on the Execution Date until to the selection of the Initial Collaboration Targets, the Targets set forth on **Schedule 3.2.1**), or the date upon which a given Program for an additional Collaboration Target commences under this Agreement, as applicable, until the earlier of (a) such time as such Program becomes a Terminated Program hereunder or (b) such time as the Parties enter into a License Agreement or Co-Co Collaboration Agreement with respect to such Program, except as otherwise expressly permitted under this Agreement, and except as and to the extent set forth in the Existing Alnylam Third Party Agreements (as such agreements are existing as of the Effective Date), each Party shall not, and shall cause its Affiliates not to (x) assign, transfer, convey, encumber (through any liens, charges, security interests, mortgages, or similar actions) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (through lien, charge, security interest, mortgage, or similar action) or dispose of, any Alnylam Patents, Alnylam Know-How, Regeneron Patents or Regeneron Know-How specifically related to such Program or any rights to any Collaboration Products under such Program (collectively, the "**Program Assets**"), except to the extent such assignment, transfer, conveyance, encumbrance or disposition would not conflict with the rights or licenses granted to the other Party hereunder (or that would be granted to such other Party pursuant to a License Agreement or Co-Co Collaboration Agreement, if such License Agreement or Co-Co Collaboration Agreement were entered into with respect to such Program in accordance with this Agreement) or (y) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to any Program Assets if such license or grant would conflict with the rights or licenses granted to the other Party hereunder (or that would be granted to such other Party pursuant to a License Agreement or Co-Co Collaboration Agreement, if such License Agreement or Co-Co Collaboration Agreement were entered into with respect to such Program in accordance with this Agreement).

4.6.2 Without limiting the provisions of Section 4.6.1, during the Research Term until such time as a given Target becomes a Collaboration Target under a Program hereunder (in which case the provisions of Section 4.6.1 shall apply), except as otherwise expressly permitted under this Agreement, and except as and to the extent set forth in the Existing Alnylam Third Party Agreements (as such agreements are existing as of the Effective Date), Alnylam shall not, and shall

cause its Affiliates not to, (a) assign, transfer, convey, encumber (through any liens, charges, security interests, mortgages, or similar actions) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (through lien, charge, security interest, mortgage, or similar action) or dispose of (i) any intellectual property specifically for (x) a given Eye Target (other than the Alnylam Reserved Target), CNS Target (other than the Alnylam Reserved Target), Reserved Liver Target, Reserved NASH Target or Pre-Cleared Target, as applicable, or (y) any siRNA Directed to any such Target as an Eye Product, CNS Product or Liver Product, as applicable, and that would otherwise be included in the Alnylam Patents or Alnylam Know-How if such Target were added as a Collaboration Target under this Agreement, or (ii) any rights specific to any product containing any such siRNA ((i) and (ii) collectively, the "**Alnylam Field Related Assets**"), except to the extent such assignment, transfer, conveyance, encumbrance or disposition would not conflict with the rights or licenses granted to Regeneron hereunder (or that would be granted to Regeneron pursuant to a License Agreement or Co-Co Collaboration Agreement, if such License Agreement or Co-Co Collaboration Agreement were entered into with respect to such Target) if such Target were added as a Collaboration Target hereunder (but with respect to requirements to obtain Control of certain Alnylam Product-Specific Patents, taking into account Section 7.1.5(a)) or (b) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to any Alnylam Field Related Assets if such license or grant would conflict with the rights or licenses granted to Regeneron hereunder (or that would be granted to Regeneron pursuant to a License Agreement or Co-Co Collaboration Agreement, if such License Agreement or Co-Co Collaboration Agreement were entered into with respect to such Target) if such Target were added as a Collaboration Target hereunder (but with respect to requirements to obtain Control of certain Alnylam Product-Specific Patents, taking into account Section 7.1.5(a)), provided that this Section 4.6.2 shall not apply to the prosecution or maintenance (including preparation, submission and withdrawal) of any Patent Rights by Alnylam or any of its Affiliates in the ordinary course.

4.7 License Agreements and Co-Co Collaboration Agreements. Notwithstanding anything to the contrary contained herein, on a Program-by-Program basis, upon execution of a License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program, the further Development, Manufacture and Commercialization of Collaboration Products Directed to the applicable Collaboration Target shall be governed by the License Agreement or Co-Co Collaboration Agreement, as applicable; but without prejudice to any rights that shall have accrued (or that may accrue as a result of activities under this Agreement) to the benefit of a Party with respect to such Program hereunder prior to entering into such License Agreement or Co-Co Collaboration Agreement.

4.8 C5 Agreements.

4.8.1 The Parties shall negotiate in good faith to enter into an agreement governing the C5 Product (the "**C5 Collaboration Agreement**") and an agreement governing the C5

Combination Product (the "**C5 Combination License Agreement**," and together with the C5 Collaboration Agreement, the "**C5 Agreements**") in accordance with the C5 Agreements Term Sheet following the Effective Date and in accordance with the timelines described in this Section 4.8. Within [***] Business Days after the Effective Date, Regeneron shall deliver an initial draft of the C5 Combination License Agreement, and within [***] after the Effective Date, Regeneron shall deliver an initial draft of the C5 Collaboration Agreement. Within [***] of its receipt of such initial drafts, Alnylam shall provide a counterproposal, if any, for such C5 Agreements, and thereafter the Parties shall use good faith efforts, including through good faith negotiations, to finalize such C5 Agreements prior to [***] of the Effective Date.

4.8.2 In the event that the Parties cannot negotiate and finalize the C5 Agreements on or prior to [***] of the Effective Date (or such longer time period as may be mutually agreed by the Parties), and provided that both Parties have been negotiating in good faith and in accordance with this Agreement, then either Party may, by written notice to the other Party, initiate the procedures described in this Section 4.8 to finalize the definitive terms and conditions of such agreement through binding arbitration as follows:

(a) Within [***] of such written notice, each Party will (i) prepare drafts of the proposed C5 Agreements to be used in such arbitration proceeding (each, an "**Arbitration Draft**" and collectively, the "**Arbitration Drafts**") and (ii) submit its respective Arbitration Drafts to the other Party, and the Parties shall, within [***] after exchanging the Arbitration Drafts, meet to determine whether they agree to enter into either Party's Arbitration Drafts or modified versions thereof.

(b) If the Parties are unable to so agree within [***] after the Parties meet pursuant to Section 4.8.2(a), then the Parties shall mutually select a neutral professional in business or licensing experienced in biopharmaceutical products with at least fifteen (15) years of experience in the pharmaceutical and life sciences industries, including the conduct of research, development and commercialization collaborations who (i) has not worked for or been engaged by either Party or its Affiliates in the seven (7)-year period immediately prior to selection of such individual, and (ii) does not own equity or debt in either Party or its Affiliates (other than equity or debt owned through a broad based mutual fund or exchange trade fund) (the "**Arbitrator**"), which Arbitrator shall be identified within [***] after the end of such [***] period. Promptly following the identification of the Arbitrator, each Party shall submit its respective Arbitration Drafts to the Arbitrator and within [***] following the receipt of the latter of such Arbitration Drafts the Arbitrator shall select one of the Arbitration Drafts for the C5 Collaboration Agreement or the C5 Combination License Agreement, as applicable; provided that, for clarity, the Arbitrator shall be limited to selecting only one or the other of the Arbitration Drafts submitted for the C5 Collaboration Agreement or the C5 Combination License Agreement, as applicable, in each case, that most closely reflects the terms and intent of the C5 Agreements Term Sheet. The determination of the Arbitrator

as to the selection of one Party's Arbitration Draft for the C5 Collaboration Agreement or the C5 Combination License Agreement, as applicable, shall be binding and conclusive upon both Parties and their Affiliates.

(c) The (i) fees of the Arbitrator and (ii) costs and expenses of the arbitration shall be paid by the Party whose Arbitration Draft was not selected by the Arbitrator.

(d) The Parties agree not to disclose to any Third Party (other than to the Arbitrator, their respective counsel and other advisors) any portion of any Arbitration Draft submitted by another Party in the course of such proceedings.

4.8.3 Prior to such time as the Parties enter into the C5 Agreements, Alnylam and its Affiliates shall not undertake any activity with respect to the C5 Product or C5 Combination Product that would be prohibited under a C5 Agreement once entered into pursuant to and as set forth in the C5 Agreements Term Sheet.

4.9 Delay for Merger Control Filing. At the written request of either Party, the effectiveness of a given License Agreement or Co-Co Collaboration Agreement will be delayed for the Parties to make any required Merger Control Filing(s) and to cause the occurrence of the Merger Control Conditions. Each Party will provide the other Party with any information (including financial information) reasonably requested by such Party for purposes of determining whether a Merger Control Filing is required. If a Party determines that a Merger Control Filing is required, then each of Regeneron and Alnylam, as required under the applicable Antitrust Law(s), will make or cause to be made such filing(s) or notification(s) as promptly as practicable (but in any event within twenty (20) Business Days of such determination). The Parties will reasonably cooperate with one another to the extent necessary in the preparation of any such Merger Control Filing. Each Party will be responsible for its own costs and expenses associated with such Merger Control Filing, and will share equally all filing fees. Each of Regeneron and Alnylam hereby covenants and agrees to use reasonable efforts to eliminate any material concern on the part of any Governmental Authority regarding the legality of the License Agreement or Co-Co Collaboration Agreement including, if required by a Governmental Authority, promptly taking all reasonable steps to remove any and all impediments to the consummation of the License Agreement or Co-Co Collaboration Agreement, including using reasonable efforts to (i) obtain government antitrust clearance or approval, (ii) cooperate in good faith with any Governmental Authority investigation, and (iii) promptly produce documents and information if requested by a Governmental Authority. Each of Regeneron and Alnylam further covenants and agrees not to take any action that will have the effect of materially delaying, impairing, or impeding, the occurrence of the Merger Control Conditions with respect to the entry of the License Agreement or Co-Co Collaboration Agreement. Notwithstanding the foregoing, nothing in this Section 4.9 (Delay for Merger Control Filing) will require either Party or such Party's Affiliates to (a) disclose to the other Party any information that is subject to obligations

of confidentiality or non-use owed to Third Parties (nor will either Party be required to conduct joint meetings with any Governmental Authority in which such information might be shared with the other Party), in each case, unless required by the applicable Governmental Authority, (b) to consent to the divestiture or other disposition of any of its or its Affiliates' assets or to consent to any other structural or conduct remedy or (c) litigate with respect to any Antitrust Law.

4.10 [***]

ARTICLE 5
GRANT OF RIGHTS

5.1 Grants to Regeneron. Subject to the terms and conditions of this Agreement, Alnylam hereby grants Regeneron:

5.1.1 during the Term of this Agreement, on a Program-by-Program basis, subject to Section 5.4.2, an exclusive (including with regard to Alnylam and its Affiliates), non-transferable (except as permitted by Section 12.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 5.3, under the Alnylam Product-Specific Patents and the Alnylam Product-Specific Know-How, to perform activities under the Candidate Discovery Plan for such Program and to Exploit the Collaboration Products under such Program in accordance with the Candidate Discovery Plan in the Field in the Territory, which license shall be fully paid-up;

5.1.2 during the Term of this Agreement, on a Program-by-Program basis, a non-exclusive, non-transferable (except as permitted by Section 12.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 5.3, under the Alnylam Core Technology Patents and the Alnylam Core Technology Know-How, to perform activities under the Candidate Discovery Plan for such Program and to Exploit the Collaboration Products under such Program in accordance with the Candidate Discovery Plan in the Field in the Territory, which license shall be fully paid-up;

5.1.3 during the Term of this Agreement, on a Program-by-Program basis, subject to Section 5.4.2, an exclusive (including with regard to Alnylam and its Affiliates), non-transferable (except as permitted by Section 12.2), fully paid-up, worldwide license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 5.3, under the Regulatory Approvals and any other Regulatory Documentation that Alnylam or its Affiliates may Control that are related to a Collaboration Product under such Program as necessary for purposes of performing any activities under the applicable Candidate Discovery Plan for such Program and for Exploiting such Collaboration Product in accordance with the applicable Candidate Discovery Plan for such Program in the Field in the Territory; and

5.1.4 a non-exclusive, non-transferable (except as permitted by Section 12.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, under the [***] to Exploit any product in the Territory that does not contain any siRNA, MicroRNA, MicroRNA antagonist or MicroRNA Mimic, or any single or double-stranded oligonucleotide designed to specifically hybridize to RNA and modulate the expression of the intended target.

Notwithstanding the foregoing in this Section 5.1, Regeneron does not receive any rights under the license grants in this Section 5.1 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Alnylam (or any of its Affiliates).

5.2 Grants to Alnylam. Subject to the terms and conditions of this Agreement, Regeneron hereby grants Alnylam:

5.2.1 during the Term of this Agreement, on a Program-by-Program basis, a non-exclusive, non-transferable (except as permitted by Section 12.2), fully paid-up, worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 5.3, under the Regeneron Technology, to perform activities under the Candidate Discovery Plan for such Program and to Exploit the Collaboration Products under such Program in accordance with the Candidate Discovery Plan in the Field in the Territory, which license shall be fully paid-up; and

5.2.2 a non-exclusive, non-transferable (except as permitted by Section 12.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, under the [***] to Exploit any product in the Territory containing siRNA (other than a Competing Product hereunder or a Competing Product (as defined in any then-existing License Agreement or Co-Co Collaboration Agreement)).

Notwithstanding the foregoing in this Section 5.2, Alnylam does not receive any rights under the license grants in this Section 5.2 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Regeneron (or any of its Affiliates).

5.3 Sublicenses. Either Party shall have the right to grant sublicenses (or further rights of reference), through multiple tiers, under the licenses and rights of reference granted to Regeneron in Section 5.1.1, Section 5.1.2, or Section 5.1.3 or to Alnylam in Section 5.2.1, as applicable; provided that any such sublicenses to Develop a Collaboration Product shall be consistent with the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement and any such sublicense agreements shall first be approved by the Joint Steering Committee pursuant to Section 2.1.2(l); provided, however, that if any such sublicense agreement is between either Party and one or more of such Party's Affiliates, then no prior approval is required. Each sublicense agreement entered into by a Party shall contain a requirement that the Sublicensee comply with confidentiality and non-use provisions that are no less stringent than Section 8.1 with

respect to the other Party's Confidential Information. Furthermore, the applicable Party shall use commercially reasonable efforts to ensure that, to the extent possible, each such sublicense agreement by it to a Sublicensee provides that any and all data and results, discoveries, inventions and other Information, whether patentable or not, arising out of the sublicense are owned by such Party or one of its Affiliates; provided that if, after using commercially reasonable efforts, the foregoing is not possible, then such Party shall ensure that it sufficiently Controls all such data and results, discoveries, inventions and other Information in order to grant the licenses to the other Party as contemplated under this Agreement. Notwithstanding any sublicense to a Sublicensee, the sublicensing Party shall remain responsible to the other Party for the performance of all of the sublicensing Party's obligations under, and compliance with, all applicable terms and conditions of, this Agreement, including any obligations delegated to its Sublicensees. For the avoidance of doubt, either Party may grant sublicenses, through multiple tiers, under the licenses granted to such Party under Section 5.1.4 or Section 5.2.2, as applicable, without the consent of the other Party and the foregoing provisions of this Section 5.3 shall not apply to such sublicenses.

5.4 No Implied License; Retention of Rights.

5.4.1 Except as expressly provided herein, nothing in this Agreement grants either Party or vests in either Party any right, title or interest in and to the Information, Patent Rights, Confidential Information, Trademarks or other intellectual property of the other Party (either expressly or by implication or estoppel), other than the license rights expressly granted hereunder and the assignments expressly made hereunder.

5.4.2 Notwithstanding anything to the contrary in this Agreement, and without limiting any rights granted or reserved to Alnylam pursuant to any other term or condition of this Agreement, Alnylam hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) all right, title and interest in and to the Alnylam Technology to (a) perform its and their obligations under this Agreement, including to perform all activities under the Candidate Discovery Plan and (b) subject to Sections 4.6 and 5.7, develop, obtain and maintain regulatory approvals for, and to manufacture, commercialize, and otherwise exploit any compound or product, other than a Collaboration Product, in any field anywhere in the world.

5.4.3 [***].

5.5 In-License Agreements.

5.5.1 Entry Into In-Licenses.

(a) [***].

(b) [***].

(c) [***].

5.5.2 Additional Alnylam In-Licenses. In the event that a Patent Right licensed to Alnylam under an Additional Alnylam In-License actually is or will be infringed by Regeneron's Development or Manufacture of a Collaboration Product in the Field and in the Territory in accordance with this Agreement, then such Additional Alnylam In-License will thereafter automatically be deemed to be an Existing Alnylam In-License on a Collaboration Product-by-Collaboration Product basis, and all rights granted to Alnylam thereunder will be deemed to be "Controlled" by Alnylam and sublicensed to Regeneron under the applicable terms of Section 5.1, effective as of the later of (a) the date the applicable Patent Right issues and (b) the date that Regeneron's Development or Manufacture of such Collaboration Product in the Field and in the Territory in accordance with this Agreement under the applicable terms of Section 5.1 would infringe such Patent Right in the absence of a license thereunder from Alnylam; provided, for clarity, [***].

5.5.3 Management of In-Licenses. Neither Party shall, and each Party shall cause its Affiliates not to, enter into any subsequent agreement or understanding with any Third Party to an In-License to which such Party or any of its Affiliates is a party that modifies, amends or terminates any such In-License, or waives any right or obligation thereunder, in any way that would adversely affect in any material respect the other Party's rights or interests under this Agreement, including by increasing any of the other Party's obligations or otherwise agreeing to any covenants or obligations imposed on the other Party that would adversely impact the other Party's business outside of this Agreement, in each case, without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed. Neither Party shall, and each Party shall cause its Affiliates not to, commit any acts or permit the occurrence of any omissions that would cause a material breach or termination of any such In-License that would adversely affect in any material respect the other Party's rights or interests under this Agreement.

5.5.4 In-Licenses. Each Party acknowledges and agrees that the sublicenses and other rights granted by the other Party to such first Party in this Agreement are subject to the terms of any In-Licenses to which such other Party or any of its Affiliates is a party. Each Party granted a sublicense pursuant to this Agreement under any of the In-Licenses of the other Party (or any of its Affiliates) (the Party granted a sublicense, the "**Sublicensed Party**," and the Party granting the sublicense, the "**Sublicensor Party**") shall comply with, and perform and take such actions as may be required to allow the Sublicensor Party to comply with, all applicable terms and conditions of the In-Licenses of the Sublicensor Party to the extent (a) applicable to (i) the Sublicensed Party's rights or obligations relating to the Development or Manufacture of Collaboration Products under this Agreement or (ii) the filing, prosecution, maintenance, extension, defense, enforcement or the further sublicensing of the Alnylam Technology (if Alnylam is the Sublicensor Party) or the

Regeneron Technology (if Regeneron is the Sublicensor Party) to the extent relevant to the Sublicensed Party's rights or obligations relating to the Development or Manufacture of Collaboration Products under this Agreement, and (b) the Sublicensed Party has been given written notice or provided a copy of such terms and conditions on or before the later of (i) the Execution Date and (ii) the date on which such In-License is first required to have been provided to the Sublicensed Party hereunder, including any such terms and conditions relating to sublicensing, patent matters, confidentiality, reporting, audit rights, indemnification and diligence. Without limiting the foregoing, (x) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of any In-License and (y) each Sublicensed Party shall prepare and deliver to the Sublicensor Party any reports required under the applicable In-Licenses of the Sublicensor Party sufficiently in advance to enable the Sublicensor Party to comply with its obligations under the applicable In-Licenses, to the extent that the Sublicensed Party had been made aware of such provisions sufficiently in advance of the date on which such compliance is required in order for such Sublicensed Party to properly prepare such reports.

5.5.5 Excluded Agreements. Notwithstanding anything herein to the contrary, Regeneron acknowledges that certain Patent Rights and Information under which Alnylam has rights are in-licensed by Alnylam under the Excluded Agreements. It is understood and agreed that no sublicense is granted to Regeneron by Alnylam under the Excluded Agreements pursuant to this Agreement, and that no Patent Rights or Information licensed to Alnylam under the Excluded Agreements will be Controlled by Alnylam under this Agreement.

5.6 Confirmatory Patent License. Each Party shall, if requested to do so by the other Party, promptly enter into confirmatory license agreements in the form or substantially the form reasonably requested by such other Party for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as the requesting Party considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Alnylam and Regeneron shall have the same rights in respect of the respective intellectual property and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

5.7 Exclusivity.

5.7.1 Exclusivity.

(a) Collaboration Target Exclusivity. On a Collaboration Target-by-Collaboration Target basis, during the Term, subject to Section 5.7.2, Section 5.7.3 and Section 5.7.4, and the remainder of this Section 5.7.1(a), and in the case of Alnylam, except as and to the extent set forth in the Existing Alnylam Third Party Agreements and in the case of Regeneron except as and to the extent set forth in the Existing Regeneron Third Party Agreements, in each case, as

existing as of the Effective Date, each Party shall not, and shall cause its Affiliates not to, (i) directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization, any Competing Product with respect to such Collaboration Target in the Field in any country in the Territory, or (ii) license, authorize or appoint any Third Party to directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization, any Competing Product with respect to such Collaboration Target in the Field in any country in the Territory.

(A) Exceptions to Exclusivity for Terminated Targets or Declined Targets. The provisions of Section 5.7.1(a)(i) and (ii) shall no longer apply to any Collaboration Target that becomes a Terminated Target or a Declined Target (or any Competing Product Directed to such Terminated Target or Declined Target, provided that such Competing Product is not also Directed to a different Collaboration Target, whereupon Section 5.7.1(a)(i) and (ii) will continue to apply).

(B) Exceptions to Exclusivity for [***].

(C) Exceptions to Exclusivity for [***].

[***].

(D) Exceptions to Exclusivity Against [***].

(E) Exceptions to Exclusivity for [***].

[***]

(A) Exceptions to Exclusivity for Terminated Targets or Declined Targets. The provisions of this Section 5.7.1(b)(i) and (ii) shall no longer apply to any Terminated Target or a Declined Target (or any Competing Product Directed to such Terminated Target or Declined Target, provided that such Competing Product is not also Directed to a different Eye Target or CNS Target, whereupon Section 5.7.1(b)(i) and (ii) will continue to apply).

(B) Exceptions to Exclusivity for Alnylam Reserved Target. The provisions of Section 5.7.1(b)(i) and (ii) shall not apply to the Alnylam Reserved Target (or any Competing Product Directed to such Alnylam Reserved Target; provided that such Competing Product is not also Directed to a different Eye Target or CNS Target, whereupon Section 5.7.1(b)(i) and (ii) will continue to apply).

(c) siRNA Sequence Exclusivity. Without limiting the provisions of Sections 5.7.1(a) and 5.7.1(b), during the Term, Alnylam shall not, and shall cause its Affiliates not to, (i) directly or indirectly, develop, commercialize or manufacture for purposes of development

or commercialization any siRNA that includes the same nucleotide sequence (or a different nucleotide sequence that functionally targets the same nucleotide sequence of the messenger RNA) as a Collaboration Product, except for [***], or (ii) license, authorize or appoint any Third Party to directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization any siRNA that includes the same nucleotide sequence (or a different nucleotide sequence that functionally targets the same nucleotide sequence of the messenger RNA) as a Collaboration Product, except for [***]; provided that in each case ((i)-(ii)), [***].

(d) License Agreements and Co-Co Collaboration Agreements. Notwithstanding the foregoing provisions of this Section 5.7.1, if a License Agreement or Co-Co Collaboration Agreement is entered into with respect to a given Program, then the foregoing provisions of this Section 5.7.1 shall no longer apply to the Collaboration Target under such Program (or any Competing Product Directed to such Collaboration Target), and, for clarity, the provisions of the License Agreement or Co-Co Collaboration Agreement, as applicable, shall thereafter apply with respect to such Collaboration Target (and any Competing Product Directed to such Collaboration Target), but without prejudice to any rights that shall have accrued (or that may accrue as a result of activities under this Agreement) to the benefit of a Party prior to entering into such License Agreement or Co-Co Collaboration Agreement. Notwithstanding the foregoing, in the event of the occurrence of a Third Party Acquisition during the Term (prior to such time as such License Agreement or Co-Co Collaboration Agreement is entered into for the applicable Program) pursuant to which there was a Competing Program or Acquisition Product as set forth in Section 5.7.2 and Section 5.7.3 with respect to the Collaboration Target that was the subject of such Program, then such Competing Program or Acquisition Product, as applicable, shall be considered a "Competing Program" or "Acquisition Product", as applicable, under the License Agreement or Co-Co Collaboration Agreement, as applicable, and the time periods set forth therein for taking action with respect to such "Competing Program" or "Acquisition Product" shall be counted beginning as of the time of the Third Party Acquisition under this Agreement, and any other adjustments contemplated by Section 5.7.2(f) shall also continue to be applicable under the equivalent provisions of the applicable License Agreement or Co-Co Collaboration Agreement.

5.7.2 Change of Control and Acquired Competing Programs and Products.

(a) If, during the Term, (i) there is a Change of Control of a Party (such Party, the "**Acquired Party**") and as of the effective date of such Change of Control, a Third Party described in the definition of "Change of Control" or any of its Affiliates (other than the Acquired Party, or the Acquired Party's Pre-Existing Affiliates) (the "**Acquirer**") is engaged, directly or indirectly, in any activities that, if carried out by the Acquired Party, would be a breach of the exclusivity obligations set forth in Section 5.7.1 (such activities, a "**Competing Program**"), or (ii) as the result of an acquisition of a Third Party or the assets of a Third Party by a Party or one or more of its Affiliates (the "**Acquiring Party**"), the Acquiring Party directly or indirectly acquires

rights to a Competing Product in the Field that would be a breach of the exclusivity obligations set forth in Section 5.7.1 (each such Competing Product, an "**Acquisition Product**" and each transaction described in subsection (i) or (ii), a "**Third Party Acquisition**"); then, the Acquired Party or Acquiring Party, as applicable, shall give the other Party (the "**Non-Acquiring Party**") express written notice thereof within ten (10) Business Days after the closing of such Third Party Acquisition and furthermore the Acquired Party or Acquiring Party, as applicable, shall in its sole discretion do one of the following after the closing of such Third Party Acquisition: (w) by the later of six (6) months after (i) such closing, (ii) the expiration of the Divestment Period pursuant to Section 5.7.2(b) and (iii) the date on which the Parties cease negotiations pursuant to Section 5.7.2(c), as applicable, terminate all development, commercialization and manufacture for purposes of development or commercialization, with respect to such Competing Program or Acquisition Product, as applicable (other than Clinical Trials that a Regulatory Authority requires the Acquired Party or Acquiring Party, as applicable, to continue, which may be continued for no more than twelve (12) months after such closing or such longer period as such Regulatory Authority requires), and deliver to the Non-Acquiring Party a notice of such termination, which notice shall include a covenant that no further development, commercialization or manufacture for purposes of development or commercialization, with respect to such Competing Program or Acquisition Product shall be performed by or on behalf of such Acquired Party or Acquiring Party, as applicable, or any of its Affiliates, to the extent the provisions of Section 5.7.1 would have prohibited such activities; provided, that an Acquired Party or Acquiring Party, as applicable, shall not be prohibited from later divesting its rights in such terminated Competing Program or Acquisition Product, as applicable, whether pursuant to the provisions of this Section 5.7.2 or otherwise; (x) divest its rights in the Competing Program or Acquisition Product to a Third Party pursuant to Section 5.7.2(b); (y) offer the Competing Product Option to the Non-Acquiring Party pursuant to Section 5.7.2(c) or (z) if applicable, exercise the right to continue the Competing Program as set forth in Section 5.7.2(d). If the Acquired Party or Acquiring Party fails to comply with one of the foregoing clauses (w), (x), (y) or (z), then, unless the Parties otherwise agree in writing, the Acquired Party or Acquiring Party, as applicable, shall be in breach of Section 5.7.1.

(b) If the Acquired Party or Acquiring Party, as applicable, chooses to divest its rights in the Competing Program or Acquisition Product, as applicable, to a Third Party, the Acquired Party or Acquiring Party, as applicable, shall commit in writing to the Non-Acquiring Party, within forty-five (45) days of the later of (i) the closing of such Third Party Acquisition and (ii) the date on which the Parties cease negotiations pursuant to Section 5.7.2(c), as applicable, to divest such Competing Program or Acquisition Product, as applicable, to a Third Party within one hundred eighty (180) days after the closing of the Third Party Acquisition, and shall do so within such one hundred eighty (180)-day period; provided, that if the Acquired Party or Acquiring Party, as applicable, fails to complete such divestiture within such one hundred eighty (180)-day period, but can demonstrate to the Non-Acquiring Party's reasonable satisfaction that it used commercially

reasonable efforts to effect such divestiture within such one hundred eighty (180)-day period, then, unless otherwise required by Applicable Law, such one hundred eighty (180)-day period shall be extended for such additional reasonable period thereafter as is necessary to enable such Competing Program or Acquisition Product, as applicable, to be in fact divested, not to exceed an additional one hundred and eighty (180) days; provided, however, that such period shall be extended for such period as is necessary to obtain any governmental or regulatory approvals required to complete such divestiture, provided that the Acquired Party or Acquiring Party, as applicable, is using good faith efforts to obtain such approvals (such period, the "**Divestment Period**"). If the Acquired Party or Acquiring Party, as applicable, does not complete the divestiture within the Divestment Period, then the Acquired Party or Acquiring Party, as applicable, shall terminate such Competing Program or Acquisition Product, as applicable pursuant to Section 5.7.2(a), or, provided such Competing Program or Acquisition Product has not previously been the subject of a Competing Product Option, offer the Non-Acquiring Party the option to include the Competing Program or Acquisition Product as a Collaboration Product under this Agreement pursuant to Section 5.7.2(c). Any divestiture of rights under this Section 5.7.2(b) shall not permit the Acquired Party or Acquiring Party, as applicable, or its Affiliates to retain any rights in (other than the right to receive payments) or involvement with the Competing Program or Acquisition Product, as applicable, including rights to direct or influence the course of development or commercialization thereof, or to contribute or receive nonpublic know-how or information of any sort with respect thereto (other than reports showing the basis for calculating payments made to the Acquired Party or Acquiring Party, as applicable, and the right to audit the accuracy of such reports); provided, that the Acquired Party or Acquiring Party, as applicable, may continue to supply the applicable Competing Product to the acquirer and provide other transitional services for a reasonable transitional period until the acquirer is able to establish its own source of supply of such Competing Product and provider for such services. If the Acquired Party or Acquiring Party, as applicable, elects to divest the Competing Program or Acquisition Product, the Acquired Party or Acquiring Party, as applicable, shall not be precluded under Section 5.7.1 from conducting any activities (either directly, or with or through any Third Party) with respect to such Competing Program or Acquisition Product during the applicable Divestment Period; provided, that any such activities are subject to appropriate firewall procedures to segregate such activities (and the personnel conducting such activities) from the activities performed by or on behalf of the Acquired Party or Acquiring Party, as applicable, pursuant to this Agreement to ensure that no Confidential Information of the Non-Acquiring Party and no other information generated under this Agreement is used in connection with such Competing Program or Acquisition Product.

(c) If the Acquired Party or Acquiring Party, as applicable, chooses to offer to the Non-Acquiring Party the option to include the Competing Program or Acquisition Product as a Collaboration Product under this Agreement (including to the extent possible under an existing Program) (the "**Competing Product Option**"), the Acquired Party or Acquiring Party,

as applicable, shall provide a Competing Product Option Data Package to the Non-Acquiring Party within thirty (30) days after the closing of such Third Party Acquisition. If the Non-Acquiring Party is interested, in its sole discretion, in exercising the Competing Product Option, it shall provide written notice thereof to the Acquired Party or Acquiring Party, as applicable, within thirty (30) days of receipt of the Competing Product Option Data Package and, promptly thereafter, the Parties shall negotiate in good faith the terms pursuant to which such Competing Program or Acquisition Product would be included as a Program or a Collaboration Product, as applicable, under this Agreement. If the Parties do not reach agreement within ninety (90) days after beginning such good faith negotiations, then the Acquired Party or Acquiring Party, as applicable, shall either terminate such Competing Program or Acquisition Product or divest its rights in such Competing Program or Acquisition Product pursuant to this Section 5.7.2.

(d) Notwithstanding anything in this Section 5.7.2 to the contrary, if during the Term there is a Third Party Acquisition as described in Section 5.7.2(a)(i), then as a limited exception to the exclusivity obligation in Section 5.7.1(a) (and in Section 5.7.1(c), but with respect to Section 5.7.1(c), this Section 5.7.2(d) shall only apply to [***] in the event that an Acquirer owns or in-licenses a Competing Program at the time of the closing of the Third Party Acquisition, then the Acquired Party may offer the Non-Acquiring Party the right to enter into a License Agreement with respect to those Programs for Collaboration Targets with respect to which the Competing Program violates the provisions of Section 5.7.1(a) (or the provisions of Section 5.7.1(c), but with respect to Section 5.7.1(c), only for such given Competing Product) by providing a written notice to the other Party (a "**Competing Program Opt-Out Election Notice**") within ten (10) Business Days after the closing of the Third Party Acquisition for the Acquired Party. In such case if so offered, the Non-Acquiring Party shall have the right, in its sole discretion, to elect to enter into a License Agreement for any such Program(s) with the Non-Acquiring Party as the "Licensee" thereunder (which election may be made by non-Acquired Party on a Program-by-Program basis), by providing written notice of such election to Acquired Party within sixty (60) days after receipt of the Competing Program Opt-Out Election Notice from the Acquired Party (the "**Competing Program Election Period**"). If the Non-Acquiring Party makes its election to enter into a License Agreement for any such Program during the Competing Program Election Period, then the Parties, subject to Section 4.9, shall enter into a License Agreement with respect to such Program (and the Collaboration Target and Collaboration Products thereunder), including completing the exhibits and schedules thereto, with the Non-Acquiring Party as the "Licensee" under such License Agreement (and, subject to Section 4.9, pending such time as the License Agreement is entered into for such Program, the Acquired Party shall, and hereby does, grant to the Non-Acquiring Party the licenses as set forth in the License Agreement with respect to such Program (including the Collaboration Target and Collaboration Products thereunder)). For the avoidance of doubt the provisions of Section 4.5 and 4.7 shall apply with respect to any such License Agreement. If the Non-Acquiring Party does not make its election to enter into the License Agreement for a given

Program during the Competing Program Election Period as set forth in this Section 5.7.2(d), then such Program shall continue hereunder in accordance with the terms and conditions of this Agreement. Notwithstanding the provisions of Section 5.7.1(a) (or Section 5.7.1(c), but with respect to Section 5.7.1(c), only for such given Competing Product), in the event that the Acquired Party provides the Competing Program Opt-Out Election Notice for the Competing Program with respect to any Collaboration Target (it being understood that, with respect to a Competing Program for any Pre-Cleared Target that is not a Collaboration Target as of the time of the closing of the Third Party Acquisition, because there is no Program that can be offered to the Non-Acquiring Party, the Acquired Party may still invoke the provisions of this Section 5.7.2(d) with respect to the applicable Competing Program, but the Non-Acquiring Party shall be deemed to have declined its right to enter a License Agreement with respect thereto; provided that if such Pre-Cleared Target is ever named as a Collaboration Target hereunder and Alnylam or any of its Affiliates (alone or with one or more Third Party(ies)) is then or thereafter developing, commercializing or manufacturing for purposes of development or commercialization, any Competing Program, then the provisions of this Section 5.7.2(d) shall again apply, *mutatis mutandis*, and Alnylam shall provide to Regeneron a Competing Program Opt-Out Election Notice with respect to the Competing Program within thirty (30) days thereafter), then the Acquirer and its Affiliates (other than Pre-Existing Affiliates) shall have the right to continue to develop, manufacture, commercialize and exploit such Competing Program without being in violation of the provisions of Section 5.7.1(a) (or Section 5.7.1(c), but with respect to Section 5.7.1(c), only for such given Competing Product); provided that if the non-Acquired Party does not elect to enter into a License Agreement for a given Program if so offered above, then the Acquirer shall or shall cause the Acquired Party to (i) continue to fulfill its obligations under this Agreement (and under any Co-Co Collaboration Agreement or License Agreement, as applicable, with respect to such Program), in all respects, (ii) ensure that the conduct of Competing Program activities is completely independent of the activities conducted under or in connection with this Agreement (and under any Co-Co Collaboration Agreement or License Agreement, as applicable, with respect to such Program), (iii) ensure that all Competing Program activities (A) do not use, access or incorporate and are not based on any Alnylam Know-How, Regeneron Know-How or other Confidential Information, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 8.1, and (B) are not covered by and do not incorporate or reference the Alnylam Patents or Regeneron Patents (or any Information or inventions disclosed in any of the foregoing) and (iv) establish reasonable internal safeguards designed to prevent any Alnylam Know-How, Regeneron Know-How or other Confidential Information from being disclosed to, or otherwise utilized by, the Acquirer or any of its Affiliates (other than Pre-Existing Affiliates), in connection with the Competing Program, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 8.1.

(e) Notwithstanding anything in this Section 5.7.2 to the contrary [***] provided that the Acquirer shall or shall cause the Acquired Party to (i) continue to fulfill its obligations under this Agreement (and under any Co-Co Collaboration Agreement or License Agreement, as applicable, with respect to such Program), in all respects, (ii) ensure that the conduct of Competing Program activities is completely independent of the activities conducted under or in connection with this Agreement (and under any Co-Co Collaboration Agreement or License Agreement, as applicable, with respect to such Program), (iii) ensure that all Competing Program activities (A) do not use, access or incorporate and are not based on any Alnylam Know-How, Regeneron Know-How or other Confidential Information, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 8.1, (B) are not covered by and do not incorporate or reference the Alnylam Patents or Regeneron Patents (or any Information or inventions disclosed in any of the foregoing), and (C) only use the Patent Rights or Information controlled by such Acquirer (or any of its Affiliates, other than the Pre-Existing Affiliates) at the time of such closing, and improvements to such Patent Rights or Information, and any other Patent Rights or Information first acquired or in-licensed by such Acquirer (or any of its Affiliates, other than the Acquired Party and its Pre-Existing Affiliates) from a Third Party after the closing of the Change of Control transaction (and improvements thereto), and (iv) establish reasonable internal safeguards designed to prevent any Alnylam Know-How, Regeneron Know-How or other Confidential Information from being disclosed to, or otherwise utilized by, the Acquirer or any of its Affiliates (other than Pre-Existing Affiliates), in connection with the Competing Program, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 8.1.

(f) Notwithstanding anything in this Agreement to the contrary, following the closing of a Change of Control of an Acquired Party, the Parties agree that (x) the Non-Acquiring Party shall not obtain rights or access to the Patent Rights or Information controlled by the Acquirer or any of the Affiliates of such Acquirer (other than the Acquired Party and its Affiliates that exist immediately prior to the closing of such Change of Control and any successor thereto (such Affiliates of the Acquired Party, the "**Pre-Existing Affiliates**")) at the time of such closing (and improvements to such Patent Rights or Information) and any other Patent Rights or Information first acquired or in-licensed by such Acquirer (or any of its Affiliates, other than the Acquired Party and its Pre-Existing Affiliates) from a Third Party after the closing of the Change of Control transaction (and improvements thereto) (so that, for clarity, none of the foregoing in this clause (x) will be treated as Controlled by Alnylam or any of its Affiliates, or by Regeneron or any of its Affiliates, as applicable, based on which Party is the Acquired Party), and (y) the Acquirer and its Affiliates (other than the Acquired Party and its Pre-Existing Affiliates) shall not obtain rights or access to the Patent Rights or Information controlled by the Non-Acquiring Party or any of its Affiliates pursuant to this Agreement, other than in connection with the Exploitation of any Collaboration Products as provided under this Agreement; provided that clause (x) of this

Section 5.7.2(f) shall not apply to any Patent Rights or Information controlled by the Acquirer or any of its Affiliates to the extent such Patent Right or Information (i) is used by or on behalf of the Acquired Party or any of its Affiliates in performing any of the Acquired Party's obligations under this Agreement; (ii) is incorporated into any Collaboration Product by or on behalf of the Acquired Party or any of its Affiliates; or (iii) was generated after the closing of such Change of Control through any use of, or access to, any Alnylam Know-How (with respect to Alnylam as the Acquired Party) or any Regeneron Know-How (with respect to Regeneron as the Acquired Party) or is otherwise Covered by any Alnylam Patent (with respect to Alnylam as the Acquired Party) or any Regeneron Patent (with respect to Regeneron as the Acquired Party); provided that, (A) with respect to Alnylam as the Acquired Party, if the Acquirer or any of its Affiliates was party to an agreement with Alnylam or any Pre-Existing Affiliate on or prior to the date of such Change of Control pursuant to which the Acquirer or such Affiliates received a license to any Information or Patent Rights controlled by Alnylam or its Pre-Existing Affiliates other than any Alnylam Product-Specific Know-How or Alnylam Product-Specific Patents, then this clause (iii) shall not apply to any Patent Rights or Information controlled or generated by Acquirer or such Affiliates under such agreement prior to such Change of Control that were not Controlled by Alnylam or any Pre-Existing Affiliate or (B) with respect to Regeneron as the Acquired Party, if the Acquirer or any of its Affiliates was party to an agreement with Regeneron or any Pre-Existing Affiliate on or prior to the date of such Change of Control pursuant to which the Acquirer or such Affiliates received a license to any Information or Patent Rights controlled by Regeneron or its Pre-Existing Affiliates other than any Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents, then this clause (iii) shall not apply to any Patent Rights or Information controlled or generated by Acquirer or such Affiliates under such agreement prior to such Change of Control that were not Controlled by Regeneron or any Pre-Existing Affiliate. Without limiting the foregoing, in all cases, the Non-Acquiring Party's rights in all Patent Rights and Information Controlled by the Acquired Party or any of its Pre-Existing Affiliates, or any of their respective successors, and all improvements thereto, shall remain licensed to such Non-Acquiring Party after the date of the closing of such Change of Control in accordance with and subject to the terms and conditions of this Agreement and shall not be affected in any manner by virtue of such Change of Control.

5.7.3 Regeneron Exceptions. Notwithstanding the exclusivity obligation in Section 5.7.1:

(a) Regeneron reserves the right to grant licenses to Third Parties to use intellectual property owned or otherwise controlled by Regeneron or its Affiliates related to research-enabling technologies, discovery-enabling technologies or manufacturing-related technologies, including Regeneron Technology, and rights to Regeneron Mice, but excluding Alnylam Technology, Regeneron Product-Specific Patents, and Regeneron Product-Specific Know-How ("**Excluded Collaboration Technology**"), which licenses, during the Term, may be for general purposes not specific to Competing Products (i.e., that is not specific to the Manufacture of any

particular Competing Product), but which may involve the exploitation of Competing Products in the Field, and such grant and any associated disclosure or provision of such intellectual property or provision of technical assistance using only such intellectual property in connection therewith shall not constitute a breach of this Agreement (including Section 5.7.1); provided that Regeneron and its Affiliates will not otherwise actively assist any Third Party (other than through the grant of such license or provision of such technical assistance) in developing or commercializing any Competing Product in the Field if doing so would not comply with Section 5.7.1, but, for clarity, may receive license fees, milestones and royalties in connection with exploitation by Third Parties of any Competing Products in the Field generated by such Third Parties.

(b) Regeneron reserves the right to grant licenses to Third Parties to use any clinical, genomic, and molecular data maintained by the Regeneron Genetics Center, other than any such data that is Excluded Collaboration Technology, for any purpose, which may involve activities with respect to Competing Products in the Field, and such grant and any associated disclosure or provision of such data or provision of technical assistance without the use of Excluded Collaboration Technology in connection therewith shall not constitute a breach of this Agreement (including Section 5.7.1); provided that, Regeneron and its Affiliates will not otherwise actively assist any Third Party (other than through the grant of such license or provisions of such technical assistance) in developing or commercializing any Competing Product in the Field if doing so would not comply with Section 5.7.1, but, for clarity, may receive license fees, milestones and royalties in connection with exploitation by Third Parties of any Competing Products in the Field generated by such Third Parties.

(c) The Parties acknowledge and agree that nothing in Section 5.7.1 prevents or limits Regeneron's or its Affiliate's rights to (i) settle any enforcement action or proceeding (including any counterclaim in any such action or proceeding), declaratory judgment action or similar action or claim, or any other litigation or proceeding involving an allegation of infringement or other violation of intellectual property or the invalidity or enforceability of any Patent Right owned or otherwise controlled by Regeneron or any of its Affiliates (other than with respect to intellectual property controlled by Regeneron or its Affiliates as a licensee of Alnylam under this Agreement), including by granting licenses or other rights under any such Patent Right to Third Parties in connection therewith or (ii) enter into an agreement to preempt, and thereby avoid the initiation of, any of the actions, proceedings, claims or other litigation set forth in clause (i), including by granting licenses or other rights under any such Patent Right to Third Parties in connection therewith; provided that, in either case ((i) or (ii)), neither Regeneron nor any of its Affiliates may grant a license or other right under any such Patent Right to a Third Party to make, have made, use, offer to sell, sell or import a generic version of a Collaboration Product in the Field, including any Generic Product, except pursuant to ARTICLE 7.

5.7.4 [***]

5.8 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Regeneron or Alnylam are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

5.9 [***]. Notwithstanding anything to the contrary contained herein [***].

5.9.1 [***]

5.9.2 [***]

5.9.3 [***]

5.9.4 [***]

5.9.5 [***]

5.9.6 [***]

5.9.7 For purposes of this Agreement, the following defined terms shall have the following meanings:

[***]

ARTICLE 6
PAYMENTS

6.1 Upfront Payment. In consideration for the rights granted to Regeneron under this Agreement, Regeneron shall pay to Alnylam within ten (10) Business Days after the Effective Date

a one-time upfront payment of Four Hundred Million Dollars ($400,000,000) (the "**Upfront Payment**").

6.2 Equity Agreements. The Parties will enter into the Equity Agreements as of the Execution Date.

6.3 Costs Generally. [***].

6.4 Regeneron Research Funding Payments.

6.4.1 On a Program-by-Program basis, Regeneron shall pay to Alnylam the following amounts upon achievement of the following Development activities:

(a) During the Research Term and during the first twelve (12) months of the Research Term Tail, upon initiation of synthesis of a Collaboration Product by Alnylam under a given Program in accordance with the Candidate Discovery Plan for such Program, Regeneron shall pay to Alnylam a one-time payment of [***]; and

(b) Upon designation of the first Lead Candidate (i.e., a Collaboration Product that satisfies the Lead Candidate Criteria or the Parties otherwise mutually agree to designate a given Collaboration Product as a Lead Candidate) under a given Program pursuant to Section 4.2, in each case, during the Research Term or Research Term Tail for the applicable Program, Regeneron shall pay to Alnylam a one-time payment of [***] (the "**Lead Candidate Payment**").

If any of the foregoing Development activities pursuant to this Section 6.4 are achieved for one or more Programs during a given Calendar Quarter, then Alnylam shall invoice Regeneron therefor after the end of the Calendar Quarter during which such activities were achieved, and Regeneron shall pay such invoice within thirty (30) days after receipt of such invoice. Each of the foregoing payments in this Section 6.4 shall be payable a maximum of one (1) time per Program regardless of the number of Collaboration Products under such Program and regardless of the number of Lead Candidates under such Program, and no additional payments shall be due hereunder for subsequent or repeated achievement of such events for such Program. For the avoidance of doubt, the maximum amount payable by Regeneron pursuant to this Section 6.4 is Five Million Dollars ($5,000,000) per Program assuming that each of the Development activities in this Section 6.4 were achieved for such Program.

6.4.2 Any amounts payable by Regeneron to Alnylam pursuant to this Section 6.4 shall be used by Alnylam solely and exclusively to fund or reimburse the Development activities for Collaboration Products by Alnylam pursuant to this Agreement (provided that with respect to any amounts paid to Alnylam pursuant to Section 6.4.1 that remain unused at the end of the Term,

such amounts shall be used to fund Development activities for Collaboration Products by Alnylam pursuant to the License Agreement or Co-Co Collaboration, as applicable), and for no other purpose.

6.5 [***]. Subject to the terms of this Section 6.5, the Lead Continuation Party will notify the other Party promptly (but in all cases within thirty (30) days) following the first achievement by the Lead Continuation Party (either under a License Agreement or a Co-Co Collaboration Agreement, as applicable) of each milestone event described below in this Section 6.5, and Regeneron shall thereafter pay to Alnylam the applicable amounts set forth below associated with the applicable milestone event in accordance with Section 6.6 (each, a "**[***]**"):

[***]	**[***] Payment**
1. [***]	One Hundred Million Dollars ($100,000,000)
2. [***]	One Hundred Million Dollars ($100,000,000)

Each of the foregoing [***] in this Section 6.5 shall be payable a maximum of one (1) time as set forth in the foregoing chart regardless of the number of Collaboration Targets achieving the applicable milestone event (i.e., a maximum of two (2) [***] may be made pursuant to this Section 6.5), and no additional [***] shall be due hereunder for subsequent or repeated achievement of such milestone event. For the avoidance of doubt, the maximum amount payable by Regeneron to Alnylam pursuant to this Section 6.5 is Two Hundred Million Dollars ($200,000,000), assuming that each of the milestone events in this Section 6.5 are achieved. In the event that (a) the Lead Continuation Party conducts a [***] for a given Eye Target or CNS Target (as applicable) but [***] was not achieved from such [***] and (b) such Lead Continuation Party thereafter Initiates a subsequent Clinical Trial that is later stage than the [***] for such Eye Target or CNS Target (as applicable) under a License Agreement or Co-Co Collaboration Agreement (as applicable) after [***]. In the event that the Parties disagree as to whether [***] has been achieved for a given [***] Target, then such dispute shall be an "Expert Dispute" and resolved by the Expert in accordance with **Schedule 1**.

6.6 Invoice and Payment of Milestone Payments. Following receipt of notification by the Lead Continuation Party to the other Party that the applicable milestone event triggering a milestone payment pursuant to Section 6.5 has been achieved, Alnylam shall invoice Regeneron for the applicable milestone payment, and Regeneron shall pay each milestone payment sixty (60) days after receipt of the invoice therefor.

6.7 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in Dollars. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars at the average rate of exchange for the Calendar Quarter to which such payment relates using the arithmetic mean of the daily rate of exchange, as

reported in *Thomson Reuters Eikon* (or any successor thereto) or any other source as agreed to by the Parties.

6.8 Taxes. Either Party may withhold from payments due to the other Party amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. In such case, the payor Party will provide the payee Party all relevant documents and correspondence, and will also provide to the payee Party any other cooperation or assistance on a commercially reasonable basis as may be necessary to enable the payee Party to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. The payor Party will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Apart from any withholding permitted under this Section 6.8, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies. Notwithstanding the foregoing, if, as a result of a Withholding Action by the paying Party (including any assignee or successor), any withholding or deduction of or on account of taxes, duties, levies, imposts, assessments, deductions, fees and other similar charges ("**Withholding**") is required by Applicable Law and the amount of such Withholding exceeds the amount of Withholding that would have been required if the paying Party had not committed the Withholding Action, then the paying Party shall pay an additional amount to the receiving Party such that, after Withholding from the payment and such additional amount, the receiving Party receives the same amount as it would have received from the paying Party absent such Withholding Action by the paying Party. For the avoidance of doubt, if as a result of a Withholding Action by a receiving Party (including any assignee or successor) the amount of Withholding under the law of the applicable jurisdiction exceeds the amount of such Withholding that would been required in the absence of such Withholding Action by the receiving Party, the paying Party shall be required to pay any additional amount only to the extent that the paying Party would be required to pay any additional amount to the receiving Party pursuant to the preceding sentence if the receiving Party had not committed such Withholding Action. For purposes of this Section 6.8, "**Withholding Action**" by a Party means (i) a permitted assignment or sublicense of this Agreement (in whole or in part) by such Party to an Affiliate or a Third Party outside of the United States; (ii) the exercise by such Party of its rights under this Agreement (in whole or in part) through an Affiliate or Third Party outside of the United States (or the direct exercise of such rights by an Affiliate of such Party outside of the United States); (iii) a redomiciliation of such Party, an assignee or a successor to a jurisdiction outside the United States; and (iv) any action by such Party that causes this Agreement or any payment to become subject to tax in a jurisdiction outside of the United States or subject any payments to Withholding in any jurisdiction that would not have been required absent such Withholding Action.

6.9 Resolution of Payment Disputes. In the event there is a dispute relating to any payment obligations or reports hereunder, the Party with the dispute shall provide the other Party

with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties will seek to resolve the dispute as promptly as possible, but no later than ten (10) Business Days after such written notice is received. If the Parties are unable to resolve such payment dispute within such period then the matter shall be resolved pursuant to Section 12.5. The Parties agree that if there is a dispute regarding any payment amount, only the disputed amount shall be withheld from the payment, and the undisputed amount shall be paid within the applicable timeframes.

6.10 Late Fee. A late fee of [***] as reported on *Thomson Reuters Eikon* (or any successor thereto) (or another source agreed to by the Parties) on the date that the applicable payment was due may be charged by the Party to whom payment is due with respect to any payment amount from the date such payment amount was originally due under the terms of this Agreement until such payment amount is actually paid by one Party to another Party unless such payment amount is disputed, in which case the foregoing late fee shall commence on the date such dispute is resolved.

6.11 Books and Records. Each Party shall (a) keep proper books of record and account in which full, true and correct entries (in conformity with Accounting Standards) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement; (b) keep such books of record and account for at least three (3) Calendar Years following the Calendar Year to which they pertain (or such longer period to the extent required by Applicable Law) and (c) keep such books of record and account to the extent related to this Agreement in a readily available and organized form to allow an independent auditor to verify the accuracy of all financial, accounting and numerical information provided in an efficient manner. To the extent a Party is not in compliance with clause (c) of this Section 6.11, such Party shall be responsible for any additional fees charged by the independent auditor to the other Party as a result of additional time spent by the independent auditor assembling or organizing such information.

6.12 Audits and Adjustments.

6.12.1 Audit. Regeneron shall have the right, upon no less than [***] days' advance written notice and at such reasonable places, times and intervals and to such reasonable extent as it shall request, not more than once during any Calendar Year, to have the books of record and account of Alnylam to the extent relating to this Agreement for the preceding [***] Calendar Years audited by an independent and nationally recognized accounting firm of its choosing and reasonably acceptable to Alnylam, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided, that absent evidence of fraud, gross negligence or willful misconduct no period may be subjected to audit more than one (1) time.

6.12.2 Results; Costs; Confidentiality. The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party by notice to the other Party within [***] days after delivery. If a Party over-billed or underpaid an amount due under this Agreement resulting in a cumulative discrepancy during any Calendar Year of more than the greater of [***] it shall also reimburse the other Party for the costs of the accounting firm to conduct such audit (with the cost of the audit to be paid by Regeneron in all other cases). Such accountants shall not reveal to Regeneron the details of its review, except for the results of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in ARTICLE 8. At the request of Alnylam prior to the audit, Regeneron shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with Alnylam obligating such accounting firm to retain all such information in confidence pursuant to such confidentiality agreement.

6.12.3 Reconciliation. If any examination or audit of the records described above discloses an overbilling or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 6.12.2, the Party that over-billed or underpaid shall pay the same to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to Section 6.12.1.

6.12.4 Binding and Conclusive. Upon the expiration of the three (3) year period following the end of any Calendar Year, the calculation of the amounts payable with respect to such Calendar Year shall be binding and conclusive upon the Parties.

6.13 Accounting Standards. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with Accounting Standards, as generally and consistently applied.

ARTICLE 7
INTELLECTUAL PROPERTY

7.1 Ownership of Intellectual Property.

7.1.1 Ownership of Technology. Subject to Section 7.1.2, as between the Parties: (a) Regeneron shall own and retain all right, title and interest in and to any and all (i) Regeneron Collaboration IP and (ii) other Information, inventions, Patent Rights, and other intellectual property rights that are owned or otherwise Controlled by Regeneron, its Affiliates or its or their Sublicensees, including the Regeneron Technology, and (b) Alnylam shall own and retain all right, title and interest in and to any and all (i) Alnylam Collaboration IP and (ii) other Information, inventions, Patent Rights, and other intellectual property rights that are owned or otherwise Controlled by Alnylam, its Affiliates or its or their Sublicensees, including the Alnylam Technology. Regeneron shall own and retain all right, title and interest in and to any and all Regeneron Background Technology.

Alnylam shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to Regeneron, without additional compensation, all right, title and interest in and to any Regeneron Background Technology Improvements as is necessary to fully effect the ownership thereof as provided for in this Section 7.1.1. Alnylam shall own and retain all right, title and interest in and to any and all Alnylam Background Technology. Regeneron shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to Alnylam, without additional compensation, all right, title and interest in and to any Alnylam Background Technology Improvements as is necessary to fully effect the ownership thereof as provided for in this Section 7.1.1.

7.1.2 Ownership of Joint Collaboration IP. As between the Parties, the Parties shall each own an equal, undivided interest in and to any and all Joint Collaboration IP. Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates and Sublicensees to so disclose, the development, making, conception or reduction to practice of any Joint Collaboration IP. Subject to the licenses and rights of reference granted under Section 5.1 and Section 5.2 and the Parties' respective exclusivity obligations under Section 5.7 and subject further to Section 4.6, (a) each Party shall have the right to Exploit the Joint Collaboration IP without a duty of seeking consent or accounting to the other Party and (b) each Party hereby grants to the other Party a non-exclusive license to such Party's interest in the Joint Collaboration IP for all purposes. Each Party shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to the other Party, without additional compensation, all such right, title and interest in and to any Joint Collaboration IP as is necessary to fully effect the joint ownership thereof as provided for in this Section 7.1.2.

7.1.3 United States Law. The determination of whether Information and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent Rights, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States irrespective of where such conception, discovery, development or making occurs. To the extent that the Applicable Law in any jurisdiction other than the United States affects the ownership of intellectual property, as a matter of law, in a manner that is inconsistent with the application of Applicable Law in the United States, the Parties shall assign, transfer and otherwise convey, to the other Party, without additional compensation, all such right, title and interest in and to any applicable intellectual property as is necessary to fully effect the ownership thereof as provided for in this Section 7.1.3.

7.1.4 Assignment Obligation. Each Party shall cause all Persons who perform Development activities (or Manufacturing activities, to the extent conducted under this Agreement)

for such Party under this Agreement to be under an obligation to assign their rights in any Information and inventions resulting therefrom to such Party, except (a) if Applicable Law requires otherwise, (b) subject to Section 3.4.5, in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment, or (c) in the case of any Third Party services provider (such as a contract manufacturer or contract research organization), with respect to any Information or inventions that constitute improvements to the background intellectual property of such Third Party, in which case ((a) through (c)), such Party shall use commercially reasonable efforts to obtain a suitable license, or right to obtain such a license, with respect to such Information and inventions, it being understood and agreed that in the case of Third Party service providers it may be commercially reasonable not to obtain a license.

7.1.5 Control of Product-Specific Know-How and Product-Specific Patents.

(a) Alnylam Obligations. Alnylam shall ensure that it sufficiently Controls (a) any and all Information owned or otherwise controlled (through license or otherwise) by Alnylam or any of its Affiliates that would otherwise be Alnylam Product-Specific Know-How if Controlled by Alnylam and (b) any and all Patent Rights owned or otherwise controlled (through license or otherwise) by Alnylam or any of its Affiliates that would otherwise be Alnylam Product-Specific Patents if Controlled by Alnylam, in each case (a) and (b), such that Alnylam can grant all rights and licenses to Regeneron hereunder (and under any applicable License Agreement and Co-Co Collaboration Agreement) with respect to such Information and Patent Rights as Alnylam Product-Specific Know-How or Alnylam Product-Specific Patents, respectively, including [***]. Notwithstanding the foregoing, but subject to the Existing Alnylam Third Party Agreements and the Additional Alnylam In-Licenses (as such agreements are existing as of the Effective Date), (i) prior to such time as a given Target first becomes a Pre-Cleared Target or Collaboration Target hereunder, solely with respect to Targets other than Listed Targets, if Alnylam or any of its Affiliates has entered into an executed written agreement with one or more Third Party(ies) for the development and commercialization of siRNA products Directed to such Target (as a specifically named Target under such agreement) (including as an option agreement or other similar agreement for such Target), then with respect to such Information and Patent Rights for such Target (other than a Listed Target), Alnylam shall only be obligated to use Commercially Reasonable Efforts to obtain such Control; (ii) with respect to Information or Patent Rights licensed to Alnylam or any of its Affiliates from a Third Party (but excluding any such Information or Patent Rights licensed to Alnylam or any of its Affiliates as part of a collaboration or similar agreement to develop or commercialize siRNA products), Alnylam shall only be obligated to use Commercially Reasonable Efforts to obtain such Control; provided that following such time as a given Target becomes a Collaboration Target, the provisions of Section 5.5.1(a) shall apply; and (iii) this Section 7.1.5(a) shall not apply to any Information or Patent Rights owned or controlled by an Acquirer or its Affiliates prior to the closing of a Change of Control of Alnylam, or to any commitments made by an Acquirer or its Affiliates prior to such closing with respect to later-developed or later-acquired Information or Patent Rights.

(b) Regeneron Obligations. Regeneron shall ensure that it sufficiently Controls (a) any and all Information owned or otherwise controlled (through license or otherwise) by Regeneron or any of its Affiliates that would otherwise be Regeneron Product-Specific Know-How if Controlled by Regeneron and (b) any and all Patent Rights owned or otherwise controlled (through license or otherwise) by Regeneron or any of its Affiliates that would otherwise be Regeneron Product-Specific Patents for such Pre-Cleared Target or Collaboration Target if Controlled by Regeneron, in each case (a) and (b), such that Regeneron can grant all rights and licenses to Alnylam hereunder (and under any applicable License Agreement and Co-Co Collaboration Agreement) with respect to such Information and Patent Rights as Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents, respectively, including with respect to the distinctions between Designated Targets and non-Designated Targets. Notwithstanding the foregoing, but subject to the Existing Regeneron Third Party Agreements (as such agreements are existing as of the Effective Date), (i) prior to such time as a given Target first becomes a Pre-Cleared Target or Collaboration Target hereunder, if Regeneron or any of its Affiliates has entered into an executed written agreement with one or more Third Party(ies) for the development and commercialization of siRNA products Directed to such Target (as a specifically named Target under such agreement) (including as an option agreement or other similar agreement for such Target), then with respect to such Information and Patent Rights for such Target, Regeneron shall only be obligated to use Commercially Reasonable Efforts to obtain such Control; (ii) with respect to Information or Patent Rights licensed to Regeneron or any of its Affiliates from a Third Party (but excluding any such Information or Patent Rights licensed to Regeneron or any of its Affiliates as part of a collaboration or similar agreement to develop or commercialize siRNA products), Regeneron shall only be obligated to use Commercially Reasonable Efforts to obtain such Control; provided that following such time as a given Target becomes a Collaboration Target, the provisions of Section 5.5.1(a) shall apply; and (iii) this Section 7.1.5(b) shall not apply to any Information or Patent Rights owned or controlled by an Acquirer or its Affiliates prior to the closing of a Change of Control of Regeneron or to any commitments made by an Acquirer or its Affiliates prior to such closing with respect to later-developed or later-acquired Information or Patent Rights.

(c) Listed Targets. From time to time during the Research Term (but no more than one (1) time per Calendar Year), [***].

7.2 Prosecution and Maintenance of Patents.

7.2.1 Prosecution and Maintenance of Product-Related Patents.

(a) Prosecution and Maintenance.

[***]

(b) Filing Countries. [***]

7.2.2 Prosecution and Maintenance of Alnylam Core Technology Patents that are not also Joint Collaboration Patents or Alnylam Delivery Patents. [***]

7.2.3 Prosecution and Maintenance of Alnylam Delivery Patents. [***]

7.2.4 Prosecution and Maintenance of Regeneron Core Technology Patents that are not also Joint Collaboration Patents. [***]

7.2.5 Cooperation. [***]

7.2.6 Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this ARTICLE 7, neither Party shall have the right to make an election under 35 U.S.C. § 102(c) when exercising its rights under this ARTICLE 7 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. § 100(h).

7.2.7 Patent Term Extension and Supplementary Protection Certificate. [***]

7.3 Enforcement of Patents and Information.

7.3.1 Notices. On a Program-by-Program basis, each Party shall promptly notify the other Party in writing of any (a) known or suspected infringement of any Alnylam Technology or Regeneron Technology or (b) unauthorized use or misappropriation of any Confidential Information or Information of a Party by a Third Party of which such Party becomes aware, in each case, to the extent such alleged infringing, unauthorized or misappropriating activities involve, as to any Collaboration Product under such Program, a Competing Product with respect thereto in the Field (the "**Competitive Infringement**").

7.3.2 Product-Related IP.

[***]

7.3.3 Alnylam Core Technology Patents and Alnylam Core Technology Know-How that are not also Joint Collaboration IP or Alnylam Delivery Patents. [***].

7.3.4 Regeneron Core Technology Patents and Regeneron Core Technology Know-How that are not also Joint Collaboration IP. [***].

7.3.5 Cooperation and Settlement. The Parties agree to cooperate fully in any Infringement Action pursuant to this Section 7.3. If a Party brings such an Infringement Action,

the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any Infringement Action in accordance with this Section 7.3 shall have the right to settle such claim only with the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed; provided, however, that such Party shall not have the right to settle such Infringement Action in a manner that involves an admission of invalidity or unenforceability with respect to Patent Rights Controlled by such other Party (including Joint Collaboration Patents), without the prior consent of the other Party, such consent to be granted or withheld in its sole discretion. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court.

7.4 Administrative Proceedings.

7.4.1 On a Program-by-Program basis, each Party shall promptly notify the other Party in writing upon receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, post-grant review, inter partes review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to any of the Product-Related Patents or Alnylam Delivery Patents. The Parties shall thereafter consult and reasonably cooperate to determine a course of action with respect to any such proceeding and shall reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms; provided, however, that, except as otherwise agreed by the Parties, and except as set forth below in Section 7.4.2, the Party that has the right to prosecute such Product-Related Patent or Alnylam Delivery Patent shall control and have final decision-making authority with respect to any such proceeding relating to such Product-Related Patent or Alnylam Delivery Patent, as applicable.

7.4.2 If any proceeding under Section 7.4.1 involves Patent Rights involved in an Infringement Action under Section 7.3.2, Section 7.3.3 or Section 7.3.4, or an invalidity or unenforceability action under Section 7.5, any decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, shall be made by the Party controlling such Infringement Action or such invalidity or unenforceability action.

7.4.3 All costs and expenses incurred in connection with any proceeding under this Section 7.4 will be borne in the same manner as costs and expenses incurred with respect to prosecution and maintenance of such Patent Rights pursuant to Section 7.2.

7.5 Invalidity or Unenforceability Defenses or Actions.

7.5.1 Notices. On a Program-by-Program basis, each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability

(except as made in an administrative proceeding under Section 7.4) of any of the Product-Related Patents or Alnylam Delivery Patents by a Third Party, including in a declaratory judgment action or similar action or claim filed by a Third Party or as a defense or as a counterclaim in any Infringement Action with respect to a Competitive Infringement initiated pursuant to Section 7.3.2, Section 7.3.3 or Section 7.3.4, in each case, of which such Party becomes aware.

7.5.2 Product-Related Patents and Alnylam Delivery Patents. [***].

7.5.3 Alnylam Core Technology Patents that are not also Joint Collaboration Patents or Alnylam Delivery Patents. [***].

7.5.4 Regeneron Core Technology Patents that are not also Joint Collaboration Patents. [***].

7.5.5 Cooperation. [***].

7.5.6 Costs and Expenses. [***].

7.6 Infringement Claims by Third Parties.

7.6.1 Notices. If the Development or Manufacture of a Collaboration Product in the Field pursuant to this Agreement results in, or may result in, an infringement action by a Third Party alleging infringement of such Third Party's intellectual property (a "**Third Party Infringement Action**"), the Party first receiving notice thereof shall promptly notify the other Party thereof in writing.

7.6.2 Defense. [***].

7.6.3 Settlement. [***].

7.6.4 Costs and Expenses; Recovery. [***].

7.7 Ownership of Corporate Names. As between the Parties, each Party shall retain all right, title and interest in and to its respective Corporate Names.

7.8 Discussion of Potential Material Intellectual Property Issues. Each Party's legal/intellectual property department shall keep the other Party's legal/intellectual property department reasonably apprised of any potential material Patent Right or other intellectual property-related issue with respect to activities under this Agreement, which may be made pursuant to a mutually acceptable and customary common interest agreement entered into by the Parties; provided that the foregoing shall not impose any duty on either Party to conduct or obtain freedom-to-operate or

validity or similar opinions of counsel or Patent Right or other intellectual property clearance searches to the extent not already conducted or obtained by such Party.

7.9 Order of Precedence. On a Program-by-Program basis, if a License Agreement or Co-Co Collaboration Agreement, as applicable, is entered into with respect to a given Program, then the provisions of such License Agreement or Co-Co Collaboration Agreement, as applicable, shall thereafter apply with respect to Alnylam Technology, Regeneron Technology and other intellectual property matters related to such Program and Collaboration Products thereunder, including prosecution and maintenance matters, enforcement and defense matters, and invalidity and unenforceability matters, and the provision of this ARTICLE 7 shall no longer apply.

ARTICLE 8
CONFIDENTIALITY AND NON-DISCLOSURE

8.1 Confidentiality Obligations. At all times during the Term and for a period of [***] years following termination or expiration hereof in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is necessary or reasonably useful for the performance of, or the exercise of such Party's rights under, this Agreement. "**Confidential Information**" means any technical, business, or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information of Third Parties, information relating to the terms of this Agreement, any Collaboration Product (including the Regulatory Documentation and Development Data), any Development or Commercialization of any Collaboration Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Regeneron Know-How (which shall be the Confidential Information of Regeneron) and Alnylam Know-How (which shall be the Confidential Information of Alnylam), as applicable), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, during the Term, (a) all Information Controlled by a Party that is specifically and solely related to Product-Specific Factors ("**Product-Specific Information**") shall be deemed to be the Confidential Information of both Parties, and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto, (b) Joint Collaboration IP shall be deemed to be the Confidential Information of both Parties, and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto, (c) [***], and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto, and (d) all Permitted Alnylam Outside Products and Permitted Alnylam Outside Product Patents shall be deemed to be the Confidential Information of Alnylam. For purposes of this Agreement, all confidential information disclosed by a Party under the terms of that certain Mutual Confidential Disclosure Agreement between the

Parties dated January 17, 2018, that is related to this Agreement or the transaction contemplated herein is hereby deemed to be the Confidential Information of such Party and will be treated as if disclosed hereunder and subject to the terms of this Agreement. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 8.1 with respect to any Confidential Information shall not include any information that:

8.1.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party or any of its Affiliates or any Person to whom the receiving Party provided such information;

8.1.2 can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality to the disclosing Party with respect to such information; provided that the foregoing exception shall not apply with respect to product regulatory documentation, Product-Specific Information or Joint Collaboration IP;

8.1.3 is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality to the disclosing Party with respect to such information; or

8.1.4 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; provided that the foregoing exception shall not apply with respect to product regulatory documentation, Product-Specific Information or Joint Collaboration IP.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

8.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

8.2.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities

regulators; provided, however, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order or required to be disclosed be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by Applicable Law; and provided further that the Confidential Information disclosed in response to such court or governmental order or as required by Applicable Law shall be limited to that information which is legally required to be disclosed in response to such court or governmental order or by such Applicable Law;

8.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for INDs pursuant to the terms of this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

8.2.3 made by the receiving Party or its Affiliates or Sublicensees to its or their attorneys, auditors, advisors, consultants, contractors, existing or prospective collaboration partners, licensees, sublicensees, or acquirers as may be necessary or reasonably useful in connection with, or to its or their existing or prospective investors, lenders or financing partners as may be necessary in connection with, the Exploitation of any Collaboration Product, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement, or to potential or actual investors, lenders, financing partners, collaboration partners, licensees, sublicensees, or acquirers as may be necessary or reasonably useful in connection with their evaluation of such potential or actual transaction; provided, however, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this ARTICLE 8 (but with respect to disclosing the terms of this Agreement to existing or prospective non-strategic financial investors, lenders or financing partners, then with a duration of confidentiality as appropriate that is no less than [***] from the date of disclosure);

8.2.4 with respect to Joint Collaboration IP made by either Party or its Affiliates as may be necessary or reasonably useful in connection with the Exploitation of any product so long as such Party or its Affiliates is not in violation of this Agreement, including under Section 5.1, Section 5.2 and Section 5.7; or

8.2.5 required under an In-License; provided that the recipient is subject in writing to substantially the same confidentiality obligations as the Parties.

8.3 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any

abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 8.3 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

8.4 Public Announcements. Following the Execution Date, the Parties shall issue a press release in a mutually agreed upon form. Neither Party shall issue any subsequent public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted) and except that a Party may, once a press release or other public written statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other public written statement without the further approval of the other Party. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Notwithstanding the foregoing, on a Program-by-Program basis, the Lead Party, its Affiliates and its and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding any Collaboration Product under such Program; provided (a) such disclosure is subject to the provisions of this ARTICLE 8 with respect to the Participating Party's Confidential Information and (b) the Lead Party shall not use the name of the Participating Party (or insignia, or any contraction, abbreviation or adaptation thereof) without the Participating Party's prior written permission. Notwithstanding the foregoing, to the extent that such disclosure describes the commencement or "top-line" results of Clinical Trials of a Collaboration Product, or the achievement of any material Development events with respect to a Collaboration Product in the Territory (each, a "**Major Event**"), the Lead Party will consider in good faith any request by the Participating Party to issue a joint press release or public disclosure with the Participating Party relating to a Major Event. Prior to making any public disclosure, to the extent practicable, the Lead Party shall provide the Participating Party with a draft of such proposed disclosure for the Participating Party's review and comment, which shall be considered in good faith by the Lead Party. Such draft shall be provided to the Participating Party at least [***] (or, to the extent faster timely disclosure of a material event is required by Applicable Law or stock exchange or stock market rules, such shorter period of time sufficiently in advance of the disclosure so that the Participating Party will have the opportunity to comment upon the disclosure and the Lead Party will be able to comply with its obligations as required by Applicable Law or stock exchange or stock market rules) prior to making any such

disclosure, for the Participating Party's review and comment, which shall be considered in good faith by the Lead Party. Without limiting the foregoing, the Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party shall be entitled to make such filings, except that the Parties shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with Applicable Law. The filing Party shall provide the non-filing Party with an advance copy of this Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider the non-filing Party's timely comments thereon and cooperate with such non-filing Party in seeking such confidential treatment and, upon the written request of the non-filing Party, shall request an appropriate extension of the term of the confidential treatment period. For the avoidance of doubt, each Party shall be responsible for its own legal and other costs in connection with any filing governed by the terms of this Section 8.4.

8.5 Publications. On a Program-by-Program basis, as between the Parties, the Lead Party shall have the sole right, in consultation with the Participating Party, to issue and control all publications in scientific journals and make scientific presentations related to any Collaboration Product under such Program. The Lead Party will consider in good faith any request by the Participating Party to publish Development results related to any Collaboration Product. The Lead Party shall provide the Participating Party with an advance copy of the proposed publication, and the Participating Party shall then have [***] days prior to submission for any publication in which to comment and to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Information belonging in whole or in part to the Participating Party or that is the Confidential Information of the Participating Party. If the Participating Party informs the Lead Party that such publication, in the Participating Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to the Participating Party, or on any Information that is Confidential Information of the Participating Party, the Lead Party shall delay or prevent such publication as follows: (i) with respect to a patentable invention, such publication shall be delayed sufficiently long (not to exceed [***] days) to permit the timely preparation and filing of a patent application; and (ii) with respect to Information that is Confidential Information of such Participating Party (other than the results of a Clinical Trial or any regulatory Information), such Information shall be deleted from the publication. The Lead Party will also consider in good faith any other comments of the Participating Party. Any publication shall include recognition of the contributions of the Participating Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

8.6 Return of Confidential Information. Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which such other Party does not retain

rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, however, the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 8.1. In the event that a given Program becomes a Terminated Program, then the provisions of this Section 8.6 shall apply, *mutatis mutandis*, to Confidential Information related solely to such Terminated Program. Notwithstanding the foregoing, in the event that the Parties have entered into a License Agreement or Co-Co Collaboration Agreement with respect to a given Program, then this Section 8.6 shall not apply with respect to Confidential Information related to such Program or the Collaboration Products thereunder.

8.7 License Agreements and Co-Co Collaboration Agreements. On a Program-by-Program basis, if a License Agreement or Co-Co Collaboration Agreement, as applicable, is entered into with respect to a given Program, then the provisions of such License Agreement or Co-Co Collaboration Agreement, as applicable, shall thereafter apply with respect to Confidential Information (including public announcements and publications) related solely to such Program and the Collaboration Products thereunder, and the provision of this ARTICLE 8 shall no longer apply. If there is Confidential Information that relates to such Program and also to other Programs hereunder, then in the event of a conflict between the provisions of (i) this Agreement, on the one hand, and (ii) the License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program, on the other hand, with respect to disclosure and non-use of such Confidential Information, the provisions of the License Agreement or Co-Co Collaboration Agreement, as applicable shall control.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations and Warranties. Alnylam and Regeneron each represents and warrants to the other, as of the Execution Date and as of the Effective Date, as follows:

9.1.1 Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

9.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party (or any of its Affiliates) is bound, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party (or any of its Affiliates).

9.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

9.1.4 No Debarment. Neither it nor any of its Affiliates, nor its or their respective employees, have been debarred or are subject to debarment.

9.1.5 No Inconsistent Obligation. It (and each of its Affiliates) is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.1.6 Governmental Consents. No authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or will be necessary to be obtained by such Party for, or in connection with, the transaction contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as set forth in Section 4.9 or Section 12.18.

9.1.7 Third Party Consents. It has obtained all necessary authorizations, consents and approvals of any Third Party that is required to be obtained by it as of the Execution Date for, or in connection with, the transaction contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as set forth in Section 4.9 or Section 12.18.

9.2 Additional Representations and Warranties of Alnylam. Except as provided in **Schedule 9.2** (which **Schedule 9.2** may be updated as of the Effective Date by Alnylam (in writing to Regeneron delivered prior to the Effective Date) with respect to any matters that first occur

between the Execution Date and the Effective Date), Alnylam further represents and warrants to Regeneron, as of the Execution Date and as of the Effective Date, that:

9.2.1 Alnylam is the sole and exclusive owner of, or otherwise Controls pursuant to an Existing Alnylam In-License (or will Control pursuant to an Additional Alnylam In-License at such time that such Additional Alnylam In-License is included as an Existing Alnylam In-License pursuant to Section 5.5.2), the Alnylam Background Technology, and all of the Alnylam Background Technology licensed to Regeneron hereunder that is solely and exclusively owned by Alnylam is free and clear of liens, charges or encumbrances other than licenses and rights granted to Third Parties that are not inconsistent with the rights and licenses granted to Regeneron under this Agreement.

9.2.2 Alnylam has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Alnylam Background Technology to grant the licenses to such Alnylam Background Technology granted to Regeneron pursuant to this Agreement.

9.2.3 [***]

9.2.4 All Alnylam Patents for which Alnylam or any of its Affiliates controls prosecution and maintenance (the "**Alnylam Managed Patents**") are filed and maintained properly and correctly and, to Alnylam's Knowledge, all applicable fees have been paid on or before any final due date for payment. Alnylam has complied with all Applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Alnylam Managed Patents.

9.2.5 To Alnylam's Knowledge, the Alnylam Patents are, or, upon issuance, will be, valid and enforceable Patent Rights.

9.2.6 [***]

9.2.7 [***]

9.2.8 Alnylam has obtained from all inventors of Alnylam Background Technology that is indicated on **Schedule 1.16** or **Schedule 1.29** as being solely and exclusively owned by Alnylam or any of its Affiliates valid and enforceable agreements that have assigned to Alnylam or its Affiliate each such inventor's entire right, title and interest in and to all such Alnylam Background Technology.

9.2.9 To Alnylam's Knowledge, the Exploitation of the Alnylam Background Technology with respect to the Collaboration Products as contemplated under this Agreement or as reasonably contemplated under any License Agreement or Co-Co Collaboration Agreement, as

applicable, if entered into in accordance with this Agreement, (a) does not and will not infringe any issued Patent Right of any Third Party or misappropriate any Information or other intellectual property of any Third Party and (b) will not infringe the claims of any published Third Party patent application when and if such claims were to issue in their current form.

9.2.10 [***]

9.2.11 **Schedule 1.108** sets forth a complete and accurate list of all agreements between Alnylam and a Third Party entered into prior to the Execution Date or Effective Date, as applicable, pursuant to which Alnylam Controls (or will Control pursuant to an Additional Alnylam In-License at such time that such Additional Alnylam In-License is included as an Existing Alnylam In-License pursuant to Section 5.5.2) Information or Patent Rights that are necessary or reasonably useful to the practice of the Alnylam Background Technology as contemplated in this Agreement or as reasonably contemplated under any License Agreement or Co-Co Collaboration Agreement, as applicable, if entered into in accordance with this Agreement. Alnylam has provided Regeneron with true and complete copies of all Existing Alnylam In-Licenses and the Additional Alnylam In-Licenses. [***]

9.2.12 [***]

9.2.13 To Alnylam's Knowledge, [***].

9.2.14 Part 1 of **Schedule 9.2.14** sets forth a true, correct and complete list of all milestone, royalty and other payment obligations under any Existing Alnylam In-License or Additional Alnylam In-License that may be borne or otherwise shared by Regeneron pursuant to this Agreement (or pursuant to any License Agreement or Co-Co Collaboration Agreement, as applicable). Part 2 of **Schedule 9.2.14** sets forth a true, correct and complete description of all terms and conditions under any Existing Alnylam In-License or Additional Alnylam In-License that (i) relate to any exclusivity or non-competition that may be applicable to, or imposed on, Regeneron (or any of its Affiliates) pursuant to this Agreement (or pursuant to any License Agreement or Co-Co Collaboration Agreement) or (ii) with respect to any Alnylam Product-Specific Patents, conflict with or are otherwise inconsistent with any of the rights granted to Regeneron pursuant to ARTICLE 7 (or that may be granted to Regeneron pursuant to Article 8 of any License Agreement or Article 8) of any Co-Co Collaboration Agreement.

9.2.15 **Schedule 9.2.15** identifies (a) all agreements pursuant to which Alnylam (or any of its Affiliates) is precluded or otherwise restricted in any way from including one or more Targets as a Collaboration Target hereunder, and (b) the identity of any Target which Alnylam (or any of its Affiliates) is precluded or otherwise restricted in any way from including as a Collaboration Target hereunder (except to the extent that Alnylam is prohibited by the terms of the applicable agreement under the foregoing clause (a) from disclosing the identity of such Target to Regeneron).

With respect to the agreements set forth on **Schedule 9.2.15**, except as expressly set forth on **Schedule 9.2.15**, all Targets that are subject to any such agreement have, as of the Execution Date, already been selected, and no new Targets may be selected or otherwise added to any such agreements. Except as expressly set forth on **Schedule 9.2.15,** neither Alnylam nor any of its Affiliates has granted any rights or licenses to any Third Party to research, develop, manufacture or commercialize any product containing an siRNA Directed to any Target that is a Pre-Cleared Target as of the Execution Date, and all Targets that are Pre-Cleared Targets as of the Execution Date can be added as Collaboration Targets hereunder without restriction.

9.3 Additional Representations, Warranties and Covenants of Regeneron. Except as provided in **Schedule 9.3**, Regeneron further represents, warrants and covenants to Alnylam, as of the Execution Date and as of the Effective Date, as follows (which **Schedule 9.3** may be updated as of the Effective Date by Regeneron (in writing to Alnylam delivered prior to the Effective Date) with respect to any matters that first occur between the Execution Date and the Effective Date):

9.3.1 Neither Regeneron nor any of its Affiliates has granted any Third Party, and neither Regeneron nor any of its Affiliates is under any obligation to grant any Third Party, any right to Exploit any Collaboration Product in the Territory, except as set forth in Section 5.7.3.

9.3.2 [***], the execution and performance of this Agreement by or on behalf of either Party or their respective Affiliates (or as reasonably contemplated under any License Agreement or Co-Co Collaboration Agreement) does not, and will not, conflict with or constitute a material breach [***].

9.4 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENT RIGHTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. FOR THE AVOIDANCE OF DOUBT, THE FOREGOING IS NOT INTENDED TO LIMIT IN ANY WAY ANY EXPRESS REPRESENTATIONS OR WARRANTIES MADE BY EITHER PARTY UNDER ANY LICENSE AGREEMENT OR ANY CO-CO COLLABORATION AGREEMENT.

9.5 Additional Covenants.

9.5.1 Compliance. Each Party and its Affiliates and Sublicensees shall conduct the Development and Manufacture of the Collaboration Products in material accordance with all

Applicable Laws and industry standards, including, to the extent applicable, current governmental regulations concerning good laboratory practices, good clinical practices and good manufacturing practices. Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

9.5.2 Debarment. Neither Party nor any of its Affiliates will use in any capacity, in connection with the performance of its obligations under this Agreement, any Person that has been debarred. Each Party agrees to inform the other Party in writing promptly if it learns that it or any Person that is performing activities in connection with activities under this Agreement is debarred or is subject to debarment, or, to the notifying Party's Knowledge, if debarment of the notifying Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the performance of its obligations under this Agreement, is threatened.

ARTICLE 10
INDEMNITY

10.1 Indemnity.

10.1.1 Alnylam's Indemnification Obligations. Alnylam shall defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees and agents ("**Regeneron Indemnitees**") from and against all loss, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs payable to a Third Party (collectively, "**Damages**"), incurred by any Regeneron Indemnitee as a result of a Third Party's claim, action, suit, settlement, or proceeding (each, a "**Claim**") against a Regeneron Indemnitee to the extent such Claim arises out of or results from:

(a) the gross negligence, recklessness, willful misconduct, or intentional wrongful acts or omissions of Alnylam or any of its Affiliates (or its or their respective agents, contractors, Sublicensees, partners, representatives or other Persons working on its or their behalf) in its or their respective performance under this Agreement, including any activities under any Candidate Discovery Plan;

(b) a breach by Alnylam of this Agreement (including the inaccuracy of any representation or warranty made by Alnylam in this Agreement);

(c) any amounts payable to a Third Party under an Alnylam In-License based on a sharing with such Third Party of amounts paid to Alnylam by Regeneron pursuant to this Agreement (e.g., any amounts payable to a Third Party that constitute a share of any sublicensing income (including a sharing of the Upfront Payment)); or

(d) the Excluded Agreements or any of the intellectual property licensed thereunder (including infringement or misappropriation thereof) with respect to the activities hereunder;

except, in the case of (a) and (b), for those Damages for which Regeneron has an obligation to indemnify Alnylam pursuant to Section 10.1.2(a) or Section 10.1.2(b), as to which Damages each Party shall indemnify the other Party and the Regeneron Indemnitees or Alnylam Indemnitees, as applicable, to the extent of its respective liability for such Damages.

10.1.2 Regeneron's Indemnification Obligations. Regeneron shall defend, indemnify and hold harmless Alnylam, its Affiliates and its and their respective officers, directors, employees and agents ("**Alnylam Indemnitees**") from and against all Damages incurred by any Alnylam Indemnitee as a result of a Claim against an Alnylam Indemnitee to the extent such Claim arises out of or results from:

(a) the gross negligence, recklessness, willful misconduct, or intentional wrongful acts or omissions of Regeneron or any of its Affiliates (or its or their respective agents, contractors, Sublicensees, partners, representatives or other Persons working on its or their behalf) in its or their respective performance under this Agreement, including any activities under any Candidate Discovery Plan;

(b) a breach by Regeneron of this Agreement (including the inaccuracy of any representation or warranty made by Regeneron in this Agreement); or

(c) any amounts payable to a Third Party under a Regeneron In-License based on a sharing with such Third Party of amounts paid to Regeneron by Alnylam pursuant to this Agreement (e.g., any amounts payable to a Third Party that constitute a share of any sublicensing income);

except, in the case of (a) and (b), for those Damages for which Alnylam has an obligation to indemnify Regeneron pursuant to Section 10.1.1(a) or Section 10.1.1(b), as to which Damages each Party shall indemnify the other Party and the Regeneron Indemnitees or Alnylam Indemnitees, as applicable, to the extent of its respective liability for such Damages.

10.2 Indemnity Procedure.

10.2.1 Notification. The Party entitled to indemnification under Section 10.1.1 or Section 10.1.2 (an "**Indemnified Party**") shall notify the Party potentially responsible for such indemnification (the "**Indemnifying Party**") within five (5) Business Days of becoming aware of any Claim asserted or threatened in writing against the Indemnified Party that could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such

notice shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that such failure materially prejudices the Indemnifying Party.

10.2.2 Control of Defense. If the Indemnifying Party elects in writing to the Indemnified Party that it will assume control of the defense of such Claim, the Indemnifying Party shall have the right to defend such Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless the Indemnified Party consents to such compromise or settlement, which consent shall not be unreasonably withheld, conditioned or delayed, and which consent shall be deemed given with respect to any Damages relating solely to the payment of money damages if such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim. If the Indemnifying Party does not elect to assume control of the defense of such Claim within forty-five (45) days of its receipt of notice thereof, or if the Indemnifying Party elects in writing to the Indemnified Party to cease maintaining control of the defense of such Claim, the Indemnified Party shall have the right upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such Claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such Claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such Claim. The Indemnified Party may not compromise or settle such Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

10.2.3 Indemnified Party's Participation. The Indemnified Party shall cooperate with the Indemnifying Party in, and may participate in, but not control, any defense or settlement of any Claim controlled by the Indemnifying Party pursuant to this Section 10.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that, if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party, on the one hand, and the Indemnified Party and Alnylam Indemnitees or Regeneron Indemnitees, as applicable, on the other hand, the Indemnifying Party shall bear such costs and expenses.

10.2.4 Expenses. With respect to Claims under Section 10.1.1 or Section 10.1.2, the costs and expenses, including fees and disbursements of counsel, (a) incurred by the Indemnifying Party, shall be the responsibility of the Indemnifying Party or (b) incurred by the Indemnified Party pursuant to the proviso in Section 10.2.3 shall be reimbursed on a Calendar

Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party or the Alnylam Indemnitees or Regeneron Indemnitees, as applicable.

10.3 Insurance. During the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by Applicable Law, each of Regeneron and Alnylam shall (a) use Commercially Reasonable Efforts to procure and maintain appropriate commercial general liability and product liability insurance in an [***] or (b) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Alnylam, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Section 10.1 or otherwise. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party.

10.4 License Agreements and Co-Co Collaboration Agreements. On a Program-by-Program basis, upon execution of a License Agreement or Co-Co Collaboration Agreement, as applicable, for such Program, the indemnification rights and obligations of the Parties with respect to such Program (including the Collaboration Target and Collaboration Products thereunder) shall thereafter be governed by the License Agreement or Co-Co Collaboration Agreement, as applicable, but without prejudice to any rights that shall have accrued (or that may accrue as a result of activities under this Agreement) to the benefit of a Party with respect to such Program (including the Collaboration Target and Collaboration Products thereunder) hereunder prior to entering into such License Agreement or Co-Co Collaboration Agreement.

ARTICLE 11
TERM AND TERMINATION

11.1 Term. Except as otherwise set forth in Section 12.18, this Agreement shall be effective as of the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until, with respect to each Program hereunder, (a) such Program becomes a Terminated Program or (b) the Parties enter into a License Agreement or Co-Co Collaboration Agreement with respect to such Program (such period, the "**Term**").

11.2 Voluntary Termination of Research Collaboration. Regeneron shall have the right, in its sole discretion, to terminate the research collaboration under this Agreement as set forth

in this Section 11.2 by providing ninety (90) days' prior written notice to Alnylam (the "**Research Collaboration Termination Notice**"). In the event Regeneron provides such Research Collaboration Termination Notice, then (a) following such time as such notice is delivered, (i) the Parties will work to promptly wind-down, in compliance with Applicable Law, all activities under any ongoing Program, and (ii) no additional new Collaboration Targets or new Programs shall be added hereunder, and (b) effective upon the ninety (90) day anniversary of the delivery of the Research Collaboration Termination Notice, (i) all Programs hereunder shall become "Terminated Programs", (ii) all Collaboration Targets hereunder shall become "Terminated Targets", and (iii) the Research Term and the Research Term Extension Period shall end. In the event that a given Program becomes a "Terminated Program" pursuant to this Section 11.2 after the first dosing of the first non-human primate with Collaboration Product in the pilot non-human primate study under such Program (but before a Lead Candidate is designated from such Program), then Regeneron shall pay to Alnylam the Lead Candidate Payment for such Program within thirty (30) days after such Program becomes a "Terminated Program" pursuant to this Section 11.2. For the avoidance of doubt, any termination of research collaboration pursuant to this Section 11.2 shall not affect any License Agreement or Co-Co Collaboration Agreement that was previously entered into, which agreements shall continue in full force and effect in accordance with their terms.

11.3 Voluntary Termination of Agreement. Regeneron may terminate this Agreement at will, in its sole discretion, in its entirety upon ninety (90) days' prior written notice to Alnylam at any time. For the avoidance of doubt, any such termination of this Agreement shall not affect any License Agreement or Co-Co Collaboration Agreement that was previously entered into, which agreements shall continue in full force and effect in accordance with their terms.

11.4 Termination for Material Breach. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") has materially breached this Agreement in a manner that fundamentally frustrates the value or essential characteristics of the transactions contemplated by this Agreement as a whole, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "**Default Notice**"). If the Breaching Party does not dispute that it has committed such a material breach under this Agreement that results in the Non-Breaching Party having a right to terminate this Agreement, then if the Breaching Party fails to cure such breach, or fails to take steps as would be considered reasonable to effectively cure such breach, within ninety (90) days after receipt of the Default Notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party disputes that it has committed a material breach under this Agreement that results in the Non-Breaching Party having a right to terminate this Agreement, the dispute shall be resolved pursuant to Section 12.5. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to have materially breached in a manner that fundamentally frustrates the value or essential characteristics of the transactions contemplated by this Agreement as a whole (an "**Adverse Ruling**"), then if the Breaching Party fails to complete the actions specified by the Adverse Ruling

to cure such material breach within ninety (90) days after such ruling, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; provided that if such compliance cannot be fully achieved within such ninety (90)-day cure period, then such cure period will be extended for a period of up to sixty (60) additional days (for a total cure period of one hundred fifty (150) days) if the Breaching Party prepares and provides to the Non-Breaching Party a reasonable written plan for curing such material breach and uses commercially reasonable efforts to cure such material breach in accordance with such written plan, and if such material breach is not cured within such one hundred fifty (150)-day period, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

11.5 Termination for Insolvency. In the event that either Party (or its ultimate parent) (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within sixty (60) days of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

11.6 Effects of Expiration or Termination.

11.6.1 Termination. In the event of (a) a termination of this Agreement in its entirety pursuant to Section 11.2, 11.3, 11.4 or 11.5, (b) in the event of a termination of this Agreement with respect to a Terminated Program pursuant to Section 3.4.1(f) as a result of Regeneron exercising its Lead Party final decision-making authority on the JSC, or (c) termination of this Agreement with respect to a Terminated Program pursuant to Section 4.3.2, in each case ((a)-(c)), the provisions of **Schedule 11.6.1** shall apply.

11.6.2 Expiration of this Agreement. In the event of expiration of this Agreement, the provisions of **Schedule 11.6.1** shall apply.

11.7 Remedies. Except as otherwise expressly provided herein, expiration or termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

11.8 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued (or that may accrue as a result of activities under this Agreement) to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations

that are expressly indicated or by their nature are intended to survive the termination or expiration of this Agreement, including this Section 11.8, Sections 2.6, 3.7.1 (for the period set forth therein), 3.7.3, 4.7, 4.10, 5.1.4 (including the last paragraph of Section 5.1 (i.e., unnumbered paragraph beginning with "Notwithstanding") as applied to Section 5.1.4 only), 5.2.2 (including the last paragraph of Section 5.2 (i.e., unnumbered paragraph beginning with "Notwithstanding") as applied to Section 5.2.2 only), 5.4, 5.6, clause (O) of 5.7.1(a)(D) (to the extent a given Target is the subject of a License Agreement or Co-Co Collaboration Agreement, as applicable; including any language in such Section 5.7.1(a)(D) to the extent necessary to give effect to such clause (O)), 5.7.1(d) (to the extent a given Target is the subject of a License Agreement or Co-Co Collaboration Agreement, as applicable), 5.8, 6.1 through 6.3 (to the extent such payments have accrued but have not been paid), 6.4.2 (to the extent such payments have accrued but not been paid or to the extent applicable to ongoing Programs under then-existing License Agreements or Co-Co Collaboration Agreements, as applicable), 6.5 (to the extent applicable to ongoing Programs under then-existing License Agreements or Co-Co Collaboration Agreements, as applicable), 6.6, 6.7, 6.8, 6.9, 6.10, 6.11 (for the period set forth therein), 6.12 (for the three (3)-year period following termination or expiration of this Agreement), 6.13, 7.1.1, 7.1.2, 7.1.3, 7.2.6, 7.7, 7.9, 8.1 (for the period set forth therein), 8.2 (for the period set forth in Section 8.1), 8.3, 8.6, 8.7, 9.4, the last sentence of 11.3, 11.6 (including, for clarity, **Schedule 11.6.1**) and 11.7; ARTICLES 1 (to the extent necessary to interpret the remaining surviving provisions, and including, for clarity, the corresponding schedules, as applicable), 10 and 12; and **Schedule 1** and **Schedule 2** of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 12
MISCELLANEOUS

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within seven (7) Business Days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

12.2 Assignment. Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party may make such an assignment without the other Party's consent to its Affiliate or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all of such Party's business, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. With respect to an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section 12.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Alnylam or Regeneron, as the case may be. In the event either Party seeks and obtains the other Party's consent to assign or delegate its rights or obligations to another Party, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

12.3 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

12.4 Governing Law, Jurisdiction and Service.

12.4.1 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Except for JSC Disputes or Expert Disputes, which are governed by Section 2.2.3 or **Schedule 1** respectively, each Party acknowledges and agrees that it must commence any action, suit or proceeding arising out of or in connection with this Agreement (other than appeals therefrom) in the jurisdiction where the other Party is incorporated or has its principal place of business, and each Party hereby waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except

in courts in such jurisdiction. The Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, with respect to any Legal Dispute, subject, however, to this Section 12.4.1 and Section 12.9.

12.4.2 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 12.6.2 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

12.5 Dispute Resolution.

12.5.1 Except as provided in Section 12.9 or the last sentence of this Section 12.5.1, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, including Legal Disputes and Expert Disputes, it shall be resolved pursuant to this Section 12.5. Notwithstanding the foregoing, (a) the Parties shall resolve all JSC Disputes solely pursuant to Section 2.2.3 and this Section 12.5 does not apply to any such JSC Disputes, and (b) the Parties shall solve any dispute relating to the execution of the C5 Agreements in accordance with Section 4.8.

12.5.2 Either Party may require that any dispute, other than JSC Disputes (which are governed by Section 2.2.3) and Expert Disputes (which are governed by **Schedule 1**), be submitted to the Executive Officers for resolution by providing written notice to the other Party formally requesting that the dispute be resolved by the Executive Officers and specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. If a dispute is referred to the Executive Officers, then the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within thirty (30) days after receiving written notification of such dispute or such longer period of time as the Executive Officers may agree in writing. Any final decision mutually agreed to by the Executive Officers with respect to a dispute and set forth in writing shall be conclusive and binding on the Parties. If the Executive Officers cannot resolve such dispute within such thirty (30) days or such other period as agreed by the Executive Officers, such dispute will be resolved as follows:

(a) with respect to any Expert Dispute, such Expert Dispute shall be resolved pursuant to the provisions of **Schedule 1**; and

(b) with respect to all other disputes (but, for clarity, excluding JSC Disputes), including Legal Disputes, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise subject, however, to Section 12.4.1 and Section 12.9.

12.6 Notices.

12.6.1 Notice Requirements. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth at its address specified in Section 12.6.2 and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand or one (1) Business Day after it is sent via a reputable international overnight courier service. Either Party may change its address by giving notice to the other Party in the manner provided above. This Section 12.6.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

12.6.2 Address for Notice.

If to Regeneron, to:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel

If to Alnylam, to:

Alnylam Pharmaceuticals, Inc.
300 Third Street
Cambridge, Massachusetts 02142
Attention: Legal Department

12.7 Entire Agreement; Amendments. This Agreement, as well as the Equity Agreements and any and all executed License Agreements and Co-Co Collaboration Agreements or other agreements executed in connection therewith, together with the schedules attached hereto and thereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. If a License Agreement or Co-Co Collaboration Agreement, as applicable, is entered into with respect to a given Program, then to the extent there is a conflict between the provisions of this Agreement and the provisions of such License Agreement or Co-Co Collaboration Agreement, as applicable, the provisions of such License Agreement or Co-Co Collaboration

Agreement, as applicable, shall control with respect to such Program (and the Collaboration Target and Collaboration Products thereunder).

12.8 LIMITATION OF DAMAGES. IN NO EVENT SHALL REGENERON OR ALNYLAM BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 12.8 IS INTENDED TO LIMIT OR RESTRICT (A) LIABILITY FOR BREACH OF SECTION 5.7.1 OR ARTICLE 8 OR (B) THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER AS SET FORTH IN SECTION 10.1 WITH RESPECT TO CLAIMS.

12.9 Equitable Relief.

12.9.1 Each Party acknowledges and agrees that the restrictions set forth in Section 4.6, Section 5.7 and ARTICLE 8 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Article may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity.

12.9.2 Each Party acknowledges and agrees that any failure of a Party to enter into a License Agreement or Co-Co Collaboration Agreement, as applicable, in accordance with the provisions of ARTICLE 4 may result in irreparable injury to such other Party for which there will be no adequate remedy at law, and in such event, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction specific performance or other injunctive relief, whether preliminary or permanent, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity.

12.9.3 Each Party hereby waives any requirement that the other Party, as a condition for obtaining any such relief (a) post a bond or other security or (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 12.9 is intended, or should be construed, to limit either Party’s right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

12.10 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

12.11 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

12.12 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

12.13 Relationship of the Parties. It is expressly agreed that Alnylam, on the one hand, and Regeneron, on the other hand, shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture, or agency. Neither Alnylam, on the one hand, nor Regeneron, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

12.14 Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

12.15 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or schedule shall mean references to such Article, Section or schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended,

replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

12.16 Schedules. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

12.17 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

12.18 Effective Date. Except with respect to Sections 4.6, 9.1, 9.2, 9.3 and 9.4 and ARTICLES 8 and 12 which shall be effective as of the Execution Date, this Agreement will not be effective until the date of the Closing of the Stock Purchase Agreement (where "Closing" will have the meaning set forth in the Stock Purchase Agreement) (such date, the "**Effective Date**"). At the election of either Party, immediately upon notice to the other Party, this Agreement will become null and void and have no further force or effect (a) in the event a Governmental Authority obtains a preliminary injunction against the Parties to enjoin the transaction contemplated by this Agreement, or (b) in the event any applicable waiting periods have not expired or been terminated, or any required approval, permit, consent, or clearance has not been obtained, under any applicable Antitrust Law(s) on or prior to the Termination Date (as defined in the Stock Purchase Agreement). Subject to Applicable Law, during the period between the Execution Date and the Effective Date, Alnylam will not, and will cause its Affiliates not to: (i) assign, transfer, license or convey in any material respect, or otherwise encumber its right, title or interest in or to, any Patent Right or Information (including by granting any option or covenant not to sue with respect thereto) that would be included as Alnylam Know-How or Alnylam Patent but for such assignment, transfer, license, conveyance amendment or encumbrance (or enter into any agreement in connection with the foregoing), other than any such assignment, transfer, license, conveyance, amendment or other encumbrance that would not conflict with or adversely impact the rights granted to Regeneron hereunder; (ii) enter into an agreement with a Third Party granting such Third Party any rights to Exploit any siRNA product Directed to any of the Pre-Cleared Targets or any of the Targets listed on **Schedule 3.2.1**; or (iii) amend, modify, terminate or waive any rights under the Existing Alnylam In-Licenses or the Existing Alnylam Third Party Agreements, other than any such amendment, modification or waiver that would not adversely affect the rights granted to Regeneron hereunder.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Execution Date.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Nouhad Husseini
Name: Nouhad Husseini
Title: Vice President

[SIGNATURE PAGE TO MASTER AGREEMENT]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Execution Date.

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ John M. Maraganore, Ph.D.
Name: John M. Maraganore, Ph.D.
Title: Chief Executive Officer

Schedule 1

Expert Resolution

[***]

Schedule 2

Certain Undertakings by Alnylam

[***]

Schedule 1.16

Alnylam Core Technology Patents

(See Attached)

Schedule 1.29

Alnylam Product-Specific Patents

- With respect to the Initial Programs: [***].
- With respect to each New Program: *[To be updated to the extent required as New Programs are added under Section 3.2.4(b).]*

[***]

[***]

Schedule 1.103

Excluded Agreements

[***]

Schedule 1.107

Existing Alnylam CMOs

[***]

Schedule 1.108

Existing Alnylam In-Licenses

[***]

Schedule 1.109

Existing Alnylam Third Party Agreements

[***]

Schedule 1.111

Existing Regeneron In-Licenses

[***]

Schedule 1.112

Existing Regeneron Third Party Agreements

[***]

Schedule 1.147

Lead Candidate Criteria

[***]

Schedule 1.197

Pre-Cleared Targets

[***]

Schedule 1.247

Reserved Liver Targets

[***]

Schedule 1.248

Initial Reserved NASH Targets

[***]

Schedule 3.2.1

Potential Initial Collaboration Targets

[***]

Schedule 3.4.5

Permitted Alnylam Third Party Providers

[***]

Schedule 7.2.1

Filing Countries

[***]

Schedule 9.2

Alnylam Disclosure Schedule

[***]

Schedule 9.2.13

Diligence Request List

[***]

Schedule 9.2.14

Certain Obligations under Existing Alnylam In-Licenses or Additional Alnylam In-Licenses

[***]

Schedule 9.2.15

Certain Target Restrictions

[***]

Schedule 9.3

Regeneron Disclosure Schedule

[***]

Schedule 11.6.1

Effects of Termination or Expiration

[***]

Exhibit A

C5 Agreements Term Sheet

[***]

Exhibit B

Form of Co-Co Collaboration Agreement

(See Attached)

Exhibit C

Form of License Agreement

(See Attached)

Exhibit 10.4.1

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

CO-CO COLLABORATION AGREEMENT

between

ALNYLAM PHARMACEUTICALS, INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of [●], [●]

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CO-CO COLLABORATION AGREEMENT

This Co-Co Collaboration Agreement (this "**Agreement**") is made and entered into effective as of [●], [●] (the "**Effective Date**") by and between Alnylam Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("**Alnylam**"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York ("**Regeneron**"). Alnylam and Regeneron are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Alnylam and Regeneron entered into that certain Master Agreement, dated as of [_____ __], 2019 (the "**Master Agreement**"), pursuant to which, among other things, Alnylam and Regeneron conducted certain research and development activities with respect to siRNAs Directed to the Target (as hereinafter defined) under a Program (as defined in the Master Agreement) for the Target (the "**Target Program**"); and

WHEREAS, pursuant to the terms of the Master Agreement, the Parties are now obligated to enter into a Co-Co Collaboration Agreement (as defined in the Master Agreement) with respect to the Target Program in order for the Parties to further collaborate on the research, development and commercialization of Collaboration Products Directed to the Target on the terms and subject to the conditions as set forth herein (each initially capitalized term as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**AAA**" has the meaning set forth in **Schedule 1**.

1.2 "**Accounting Standards**" means, with respect to either Party, generally accepted accounting principles as applicable in the United States or International Financial Reporting Standards of the International Accounting Standards Board, in each case, as generally and consistently applied throughout such Party's organization. Each Party shall promptly notify the other Party in writing if such Party changes the Accounting Standards pursuant to which its records are maintained.

1.3 "**Acquired Party**" has the meaning set forth in Section 6.7.2(a).

1.4 "**Acquirer**" has the meaning set forth in Section 6.7.2(a).

1.5 "**Acquiring Party**" has the meaning set forth in Section 6.7.2(a).

1.6 "**Acquisition Product**" has the meaning set forth in Section 6.7.2(a).

1.7 "**Additional Alnylam In-Licenses**" means the agreements identified in Section 2 of **Schedule 1.107**.

1.8 "**Adverse Ruling**" has the meaning set forth in Section 12.2.

1.9 "**Affiliate**" means, with respect to a Person, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person for so long as such Person controls, is controlled by or is under common control with such first Person, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management or policies of such entity.

1.10 "**Agreement**" has the meaning set forth in the preamble hereto.

1.11 "**Alliance Manager**" has the meaning set forth in Section 2.10.

1.12 "**Alnylam**" has the meaning set forth in the preamble hereto.

1.13 "**Alnylam Background Technology**" means (a) Information that is necessary or reasonably useful to Exploit any Collaboration Product and (b) Patent Rights that Cover any Collaboration Product or the Exploitation of any Collaboration Product, in each case, ((a) and (b)), that are Controlled by Alnylam or its Affiliates during the Term, but excluding Alnylam Collaboration IP and Alnylam's interest in the Joint Collaboration IP. [***]

1.14 "**Alnylam Background Technology Improvements**" means any developments, enhancements, modifications or other improvements to, or progeny, mutants, fragments, or derivatives of the Alnylam Background Technology that (a) are made by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement, and (b) with respect to any of the foregoing constituting (i) Information, are not specifically and solely related to any Product-Specific Factor and (ii) Patent Rights, do not include any claim the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.15 "**Alnylam Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that is conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by individuals who are employees, agents or consultants of Alnylam or its Affiliates or its or their Sublicensees, in each case, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a). Alnylam Collaboration IP excludes Alnylam's interest in Joint Collaboration IP and any Regeneron Background Technology Improvements. Patent Rights constituting Alnylam Collaboration IP are either Alnylam Core Technology Patents or Alnylam Product-Specific Patents, as the case may be.

1.16 "**Alnylam Core Technology Know-How**" means Alnylam Know-How other than Alnylam Product-Specific Know-How.

1.17 "**Alnylam Core Technology Patents**" means Alnylam Patents (other than Alnylam Product-Specific Patents), including those Patent Rights set forth on **Schedule 1.17**.

1.18 "**Alnylam Cost Report**" has the meaning set forth in Section 7.2.10.

1.19 ["**Alnylam Delivery Patents**" has the meaning set forth in Section 8.2.3.][1]

1.20 "**Alnylam In-License**" means any (a) Existing Alnylam In-License; (b) Product-Specific In-License between Alnylam (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent that such agreement is designated as an Alnylam In-License pursuant to Section 6.5.1(a); or (c) Core Technology In-License between Alnylam (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent such agreement is designated as an Alnylam In-License pursuant to Section 6.5.1(c) or Section 6.5.1(d). In the event that a given Product-Specific In-License (as defined in the Master Agreement) or Core Technology In-License (as defined in the Master Agreement) between Alnylam (or its Affiliates) and a Third Party was designated to be an Alnylam In-License (as defined in the Master Agreement) for the Target Program pursuant to the Master Agreement, then such agreement shall also be an Alnylam In-License for this Agreement (as a Product-Specific In-License or Core Technology In-License, as applicable, but shall not be an Existing Alnylam In-License).

[1] Note to Draft: Include this definition only if the Target is a CNS Target.

1.21 "**Alnylam Indemnitees**" has the meaning set forth in Section 11.1.2.

1.22 "**Alnylam Internal Manufacturing Costs**" has the meaning set forth in the definition of "Minimum Internal Manufacturing Requirements".

1.23 "**Alnylam Know-How**" means (a) the Information included in the Alnylam Collaboration IP; (b) Alnylam's interest in the Information included in the Joint Collaboration IP; and (c) the Information included in Alnylam Background Technology or in any Alnylam Background Technology Improvements that is not in the public domain or otherwise generally known.

1.24 "**Alnylam Managed Patents**" has the meaning set forth in Section 10.2.4.

1.25 "**Alnylam Manufacturing Technology**" means Alnylam Technology relating to the Manufacturing Process of a Collaboration Product that is Controlled by Alnylam or its Affiliates during the Term.

1.26 "**Alnylam Patents**" means (a) the Patent Rights included in the Alnylam Collaboration IP, (b) Alnylam's interest in the Joint Collaboration Patents and (c) the Patent Rights included in any Alnylam Background Technology or in any Alnylam Background Technology Improvements.

1.27 "**Alnylam Product-Specific Know-How**" means Alnylam Know-How that is specifically and solely related to Product-Specific Factors.

1.28 "**Alnylam Product-Specific Patents**" means the Alnylam Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor, including those Patent Rights set forth on **Schedule 1.28**. For clarity, Alnylam Product-Specific Patents exclude [***].

1.29 "**Alnylam siRNA Platform**" means Alnylam Background Technology that relates generally to Alnylam's siRNA platform and is not primarily related to any Collaboration Product.

1.30 "**Alnylam Specific Activities**" means, [***].

1.31 "**Alnylam Specific Activities Costs**" means, if Alnylam exercises its Opt-Out Right, the Out-of-Pocket Costs and Development FTE Costs incurred by Alnylam in accordance with a pre-agreed plan and budget in connection with any Alnylam Specific Activities after Alnylam exercises its Opt-Out Right, but excluding, in all cases, any costs with respect to the Ongoing Candidate Discovery Development Activities. For purposes of the use of the term "Development FTE Costs" in this definition, references to a Development Plan and Budget shall be deemed references to the foregoing pre-agreed plan and budget.

1.32 "**Alnylam Technology**" means, collectively, Alnylam Know-How and Alnylam Patents.

1.33 "**Alnylam Termination Core Technology Know-How**" means Alnylam Termination Know-How other than Alnylam Termination Product-Specific Know-How.

1.34 "**Alnylam Termination Core Technology Patents**" means Alnylam Termination Patents other than Alnylam Termination Product-Specific Patents.

1.35 "**Alnylam Termination Know-How**" means any Alnylam Know-How existing as of the effective date of termination of this Agreement that (a) is not in the public domain or otherwise generally known and (b) is necessary or reasonably useful to further Exploit a Terminated Product (i) as such Terminated Product exists as of the effective date of termination of this Agreement or (ii) based on the Development Plan and Budget in effect as of the effective date of termination of this Agreement.

1.36 "**Alnylam Termination Patents**" means (a) any Alnylam Patents existing as of the effective date of termination of this Agreement that are necessary or reasonably useful to Exploit a Terminated Product (i) as such Terminated Product exists as of the effective date of termination of this Agreement or (ii) based on the Development Plan and Budget in effect as of the effective date of termination of this Agreement, and (b) any Patent Rights that claim priority to any Alnylam Patents in clause (a).

1.37 "**Alnylam Termination Product-Specific Know-How**" means Alnylam Termination Know-How that is specifically and solely related to Product-Specific Factors.

1.38 "**Alnylam Termination Product-Specific Patents**" means the Alnylam Termination Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.39 "**ANDA Act**" has the meaning set forth in Section 8.3.5.

1.40 "**Anticipated FCS Date**" means, with respect to a Collaboration Product and a country, the date agreed upon by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) in advance as the expected date of First Commercial Sale of such Collaboration Product in such country. The JSC shall agree upon such date twenty-four (24) months in advance of its expected occurrence. In the event that Development timelines are shortened such that the JSC is unable to anticipate the expected date of the applicable First Commercial Sale twenty-four (24) months in advance of its expected occurrence, the JSC shall attempt to agree upon the expected date of such First Commercial Sale as soon as practicable after the JSC determination of the filing date for the Drug Approval Application for such Collaboration Product in such country.

1.41 "**Anticipated IND Submission Date**" has the meaning set forth in Section 3.1.3(a).

1.42 "**API**" means any active pharmaceutical (including biological) ingredient or component (but excluding, for clarity, an adjuvant or excipient).

1.43 "**Applicable Law**" means applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time.

1.44 "**ASO**" means a single-stranded antisense oligonucleotide.

1.45 "**Baseline Annual Commercialization Plan and Budget**" means the initial Commercialization Plan and Budget approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) for a given Calendar Year (plus any partial Calendar Year, if applicable, as set forth in Section 4.2.2(b)) for the binding portion of such Commercialization Plan and Budget, and any amendment thereto, that was approved by the JSC by consensus or the Executive Officers pursuant to Section 2.6.3(b) (i.e., without the Lead Party exercising its final decision-making authority).

1.46 "**Baseline Annual Development Plan and Budget**" means, with respect to a Development Plan and Budget, (a) the initial Pre-Clinical Plan and Budget, the initial Phase 1 Development Plan and Budget, the initial Phase 2 Development Plan and Budget or the initial Late Stage Development Plan and Budget, as applicable, for a given Calendar Year approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) for the binding portion of such Development Plan and Budget, and (b) any amendment thereto, that was approved by the JSC by consensus or the Executive Officers pursuant to Section 2.6.3(b) (i.e., without the Lead Party exercising its final decision-making authority) or deemed approved by the Participating Party pursuant to Section 3.2.2(b) [or approved pursuant to Section 2.6.3(b)(vi)][2].

1.47 "**Breaching Party**" has the meaning set forth in Section 12.2.

1.48 "**Business Day**" means a day other than a Saturday, Sunday or another day of the week on which commercial banks in New York, New York or Boston, Massachusetts, are authorized or required by Applicable Law to remain closed.

1.49 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

[2] Note to Draft: Include this bracketed language only in Co-Co Collaboration Agreements where (1) Alnylam is the initial Lead Party and (2) the Target Program was a CNS Program under the Master Agreement.

1.50 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.51 "**Change of Control**" means, with respect to a Party (or its ultimate parent), (a) a merger, acquisition, consolidation or reorganization of such Party (or its ultimate parent) with a Third Party that results in the voting securities of such Party (or its ultimate parent) outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the "beneficial owner" (as such term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder (or, in each case, any successor thereto), except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party (or its ultimate parent), or (c) the sale or other transfer to a Third Party, whether directly or indirectly by a Party or an Affiliate thereof, of all or substantially all of such Party's (or its ultimate parent's) business.

1.52 "**Claim**" has the meaning set forth in Section 11.1.1.

1.53 "**Clinical Data**" means all Information with respect to any Collaboration Product that is made, collected, or otherwise generated under or in connection with Clinical Trials, including any data, reports, and results with respect thereto.

1.54 "**Clinical Supply Cost**" means the Manufacturing Costs for the Early Stage Supply Requirements or the Late Stage Development Supply Requirements, as applicable, [***].

1.55 "**Clinical Trial**" means (a) any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or Registration Enabling Trial, (b) such other tests and studies in human subjects that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Collaboration Product for an indication, including tests or studies that are intended to expand the Product Labeling for such Collaboration Product with respect to such indication and (c) any open label extension study of a Collaboration Product.

1.56 "**Co-Co Collaboration Agreement**" means any Co-Co Collaboration Agreement (as defined in the Master Agreement) that is entered into by the Parties (or their respective Affiliates) pursuant to the Master Agreement, but excluding this Agreement.

1.57 "**Collaboration Product**" means any product containing an siRNA Directed to the Target as a Relevant Organ Product that is Developed under and in accordance with the Master Agreement or this Agreement [***].

1.58 "**Combination Product**" means a Collaboration Product that is comprised of or contains an siRNA Directed to the Target as an API together with one or more other APIs and is sold either as (i) a fixed dose, (ii) separate doses in a single package or (iii) separate doses in separate packages but for a single price.

1.59 "**Commercial Overhead Charge**" means, [***].

1.60 "**Commercial Supply Requirement**" means the quantities of Collaboration Products that are reasonably required to fulfill requirements for commercial sales in the Territory, and other Commercialization uses with respect to the Collaboration Products in the Territory.

1.61 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Collaboration Product, including activities related to marketing, promoting, distributing, and importing such Collaboration Product, and interacting with Regulatory Authorities regarding any of the foregoing after such Collaboration Product has received Regulatory Approval, including seeking Pricing Approvals, maintaining Regulatory Approvals, conducting Non-Approval Trials, commercial pharmacovigilance and health outcomes research and publishing scientific studies other than in connection with Development. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization.

1.62 "**Commercialization Budget**" has the meaning set forth in Section 4.2.2.

1.63 "**Commercialization Plan and Budget**" means the three (3) year rolling comprehensive plan for the worldwide Commercialization of the Collaboration Products, which shall include the following:

1.63.1 the overall strategy for Commercializing the Collaboration Products, including target product profiles, branding, positioning, Promotional Materials, field force size and core messages for the Collaboration Products in the Territory;

1.63.2 strategies for the Detailing and promotion of the Collaboration Products in the Territory;

1.63.3 market and sales forecasts for the Collaboration Products;

1.63.4 Non-Approval Trials; and

1.63.5 anticipated timeline and Commercialization Budget for the Commercialization of the Collaboration Products.

1.64 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development, Commercialization, or Manufacturing activities with respect to a Collaboration Product by a Party or other applicable activities by a Party hereunder, the carrying out of such activities in a diligent manner using efforts and resources [***] devote to products of similar market potential at a similar stage in development or product life, taking into account all scientific, commercial, and other factors that such Party and its Affiliates would take into account, including issues of safety and efficacy, expected and actual cost and time to develop, expected and actual profitability, expected and actual competitiveness of alternative products (including generic products) in the marketplace, the nature and extent of expected and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected likelihood of regulatory approval, the expected and actual reimbursability and pricing, and the expected and actual amounts of marketing and promotional expenditures required, [***]. "Commercially Reasonable Efforts" shall be determined on a country-by-country basis.

1.65 "**Competing Product**" means [***].

1.66 "**Competing Product Option**" has the meaning set forth in Section 6.7.2(c).

1.67 "**Competing Product Option Data Package**" means [***].

1.68 "**Competing Program**" has the meaning set forth in Section 6.7.2.

1.69 "**Competitive Infringement**" has the meaning set forth in Section 8.3.1.

1.70 "**Confidential Information**" has the meaning set forth in Section 9.1.

1.71 "**Control**" means, with respect to a Party and any item of Information, Regulatory Documentation, material, Patent Right, or other intellectual property right, the possession by such Party or any of its Affiliates of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 6.1 or Section 6.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent Right, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party; provided, that, with respect to rights to any Third Party's Information, Patent Rights or other intellectual property rights that are licensed to, or otherwise obtained by, (a) a Party or its Affiliates pursuant to a Product-Related In-License entered

into by such Party or any of its Affiliates after the Effective Date, or (b) Alnylam or its Affiliates pursuant to any Additional Alnylam In-License, such Third Party's Information, Patent Rights or other intellectual property rights shall be deemed not to be under the Control of such Party or its Affiliates, or Alnylam or its Affiliates, respectively, unless and until the agreement pursuant to which such rights are obtained becomes an In-License pursuant to Section 6.5.1(a), Section 6.5.1(c), Section 6.5.1(d) or Section 6.5.2, as applicable.

1.72 [***]

1.73 [***]

1.74 "**Core Technology In-License**" means a Product-Related In-License that is not a Product-Specific In-License.

1.75 "**Corporate Names**" means (a) with respect to Alnylam, the Trademarks and logos as Alnylam may designate in writing to Regeneron from time to time and (b) with respect to Regeneron, the Trademarks and logos as Regeneron may designate in writing to Alnylam from time to time.

1.76 "**Cost of Goods Sold**" means, with respect to a given Calendar Quarter, the aggregate Manufacturing Costs (calculated in accordance with Accounting Standards and **Schedule 1.165**) for all Collaboration Products sold in the Territory during such Calendar Quarter; [***].

1.77 "**Cover**" or "**Covering**" means, as to a product and Patent Rights, that, in the absence of a license granted under, or ownership of, such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights or, as to a pending claim included in such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights if such pending claim were to issue in an issued patent.

1.78 "**Damages**" has the meaning set forth in Section 11.1.1.

1.79 "**Deadlocked Dispute**" has the meaning set forth in Section 2.6.3(b)(ii).

1.80 "**Default Notice**" has the meaning set forth in Section 12.2.

1.81 "**Detail**" means a face-to-face contact between a sales representative and a physician or other medical professional licensed to prescribe drugs (including a nurse practitioner or physician assistant with prescribing authority) (a "**Healthcare Prescriber**"), but excluding, for clarity: (a) e-details; (b) presentations made at conventions or to any group of more than five (5) Healthcare Prescribers or other office staff members involved in the prescribing or reimbursement of a Collaboration Product; (c) a delivery of savings cards or coupons without discussion with a

Healthcare Prescriber or other office staff member involved in the prescribing or reimbursement of a Collaboration Product; and (d) activities of medical science liaisons. When used as a verb, "**Detail**" or "**Detailing**" means to engage in a Detail.

1.82 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, Manufacturing scale-up, qualification and validation (but excluding such scale-up, qualification and validation with respect to establishing, or otherwise causing to become operational, any Manufacturing facilities), quality assurance/quality control, Clinical Trials, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing, medical affairs, medical information, medical education, health economic and outcomes research, market research, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. Development also includes the foregoing activities, if any, with respect to any devices (including diagnostics) designed for use with a Collaboration Product (which activities, if any, shall be set forth in the relevant Development Plan and Budget). Development does not include conducting Non-Approval Trials. When used as a verb, "**Develop**" means to engage in Development.

1.83 "**Development Budget**" has the meaning set forth in Section 3.1.7(a).

1.84 "**Development Costs**" means the sum of the following items, in each case, incurred by a Party for the Development of the Collaboration Products in accordance with this Agreement and the applicable Development Plan and Budget:

1.84.1 Out-of-Pocket Costs (including fees and expenses) for obtaining INDs and Regulatory Approvals for the Collaboration Products under this Agreement;

1.84.2 Development FTE Costs;

1.84.3 Out-of-Pocket Costs without markup for contractors performing Development activities under this Agreement;

1.84.4 Out-of-Pocket Costs related to Clinical Trials conducted pursuant to a Development Plan and Budget, including the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not already included in the Clinical Supply Costs;

1.84.5 Clinical Supply Costs;

1.84.6 Out-of-Pocket Costs incurred for (a) Manufacturing process, formulation, cleaning, and shipping development and validation, (b) Manufacturing scale-up and improvements, (c) stability testing, (d) quality assurance/quality control development, and (e) internal and Third Party costs and expenses incurred in connection with (i) qualification and validation of Third Party contract manufacturers and vendors (including Third Party fillers, packagers, labelers, distributors and warehousing) and (ii) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, the transfer of process and Manufacturing technology and analytical methods, scale-up to First Commercial Sale, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections and obtaining any comparator agent or product for use in Clinical Trials (in each case, to the extent not included in Clinical Supply Costs or Cost of Goods Sold); in each case for a Collaboration Product under this Agreement, except that unless otherwise agreed to by the Parties, any capital expenditures incurred in providing capacity for the Manufacture of Collaboration Products, including costs related to validation batches that are the first validation for the applicable Manufacturing facility, shall be treated in accordance with **Schedule 1.165** and shall not be included as Development Costs; provided that notwithstanding the foregoing, except with respect to the Manufacturing Technology Transfer Costs (which shall be handled in accordance with Section 5.5.1) [***];

1.84.7 any In-License Payments to the extent attributable to the Development of Collaboration Products (to the extent not otherwise included in Shared Commercial Expenses); and

1.84.8 any other costs or expenses directly related and specifically attributable to the Development of a Collaboration Product and specifically identified and included in a Development Plan and Budget or included as Development Costs under or in connection with this Agreement.

If any of the foregoing costs benefit both Collaboration Product(s) and other products or activities of a Party (for example, if an In-License is not exclusively of benefit to Collaboration Products), then the applicable Party incurring such costs shall apportion such costs in a manner that fairly and reasonably reflects the benefit to the Collaboration Products and the other products or activities of such Party; provided that, notwithstanding the foregoing, [***]. Each Party shall disclose both the total costs incurred and the apportionment in the information reported under Section 7.1.3(b) for review by the other Party. At the request of the other Party, the Party making the apportionment shall provide additional reasonable supporting documentation and make its personnel reasonably available to answer questions. Any dispute regarding such apportionment shall be a Financial Dispute.

In no event shall the same costs be included more than once in Development Costs under this Agreement, even if such costs are of benefit to multiple Collaboration Products.

1.85 "**Development Data**" has the meaning set forth in Section 3.4.2.

1.86 "**Development FTE Cost**" means, for all Development activities performed in accordance with a Development Plan and Budget, including regulatory activities, the product of (a) the number of FTEs required for such Development activities as set forth in such approved Development Plan and Budget and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs without markup.

1.87 "**Development FTE Rate**" means [***] in the Calendar Year ending December 31, 2019, such amount to be adjusted as of January 1, 2020 and annually thereafter by the average of the percentage increases or decreases, if any, in the U.S. CPI for the twelve (12) months ending June 30 of the Calendar Year prior to the Calendar Year for which the adjustment is being made. The Development FTE Rate shall be inclusive of FTE Costs and Expenses. The JFC may determine a separate FTE rate for Development personnel located outside the United States, including an appropriate indexed adjustment mechanism with respect thereto.

1.88 "**Development Payment Report**" means the report prepared by the Lead Party each Calendar Quarter in accordance with Section 7.1.3(f) that sets forth in reasonable detail, (a) the Development Costs incurred by the Parties for such Calendar Quarter and (b) the Quarterly Development True-Up for such Calendar Quarter calculated in accordance with **Schedule 7.1.1**. If an item is included in one Development Payment Report, in no event shall the same item be included in a subsequent Development Payment Report.

1.89 "**Development Phase Budget**" means, with respect to a Development Plan and Budget, the number expressed in Dollars that is equal to the estimated total Development Costs for the corresponding Development Phase Budget Period set forth in (a) the initial Pre-Clinical Plan and Budget, or the initial Phase 1 Development Plan and Budget, or the initial Phase 2 Development Plan and Budget, or the initial Late Stage Development Plan and Budget, as applicable, approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) and (b) any amendment to any such estimates approved by the JSC by consensus or the Executive Officers pursuant to Section 2.6.3(b) (i.e., without the Lead Party exercising its final decision-making authority) or deemed approved by the Participating Party pursuant to Section 3.2.2(b) [or approved pursuant to Section 2.6.3(b)(vi)][3].

[3] Note to Draft: Include this bracketed language only in Co-Co Collaboration Agreements where (1) Alnylam is the initial Lead Party and (2) the Target Program was a CNS Program under the Master Agreement.

1.90 "**Development Phase Budget Period**" means (a) with respect to the Pre-Clinical Development Plan and Budget, the period from the Effective Date through the acceptance by the applicable Regulatory Authority in a Major Market Country (or the EMA pursuant to the centralized approval procedure, or in any other country identified in the Pre-Clinical Plan and Budget in which the Parties intend to file an IND for a Collaboration Product) of the first IND for the first Collaboration Product, (b) with respect to the Phase 1 Development Plan and Budget, the period beginning immediately after the acceptance by the applicable Regulatory Authority in a Major Market Country (or the EMA pursuant to the centralized approval procedure, or in any other country identified in the Pre-Clinical Plan and Budget in which the Parties intend to file an IND for a Collaboration Product) of the first IND for the first Collaboration Product and continuing up to the Phase 1 Completion Date, (c) with respect to the Phase 2 Development Plan and Budget, the period beginning immediately after the Phase 1 Completion Date and continuing up to the Phase 2 Completion Date and (d) with respect to the Late Stage Development Plan and Budget, beginning immediately after the Phase 2 Completion Date and continuing up to the Anticipated FCS Date in the first Major Market Country.

1.91 "**Development Plan and Budget**" means each of the Pre-Clinical Plan and Budget, the Phase 1 Development Plan and Budget, Phase 2 Development Plan and Budget and the Late Stage Development Plan and Budget.

1.92 "**Direct Costs**" has the meaning set forth in **Schedule 1.165**.

1.93 "**Directed to**" means, with respect to siRNA and the Target, that such siRNA binds to and interferes with the function of any messenger RNA encoded by the Target. For clarity, [***].

1.94 "**Divestment Period**" has the meaning set forth in Section 6.7.2(b).

1.95 "**Dollars**" or "**$**" means United States Dollars.

1.96 "**Drug Approval Application**" means a New Drug Application (an "**NDA**") as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application (an "**MAA**") filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.97 "**Early Stage Supply Requirements**" means the quantities of Collaboration Products (and placebo) that are reasonably required by either Party to perform its Development activities under the Pre-Clinical Plan and Budget, Phase 1 Development Plan and Budget and Phase 2 Development Plan and Budget.

1.98 "**Effective Date**" means the effective date of this Agreement as set forth in the preamble hereto.

1.99 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.100 "**European Union**" means the organization of member states of the European Union, as it may be constituted from time to time; provided that for the purposes of this Agreement the United Kingdom and any other country that is a member of the European Union on the Effective Date, shall be deemed to be a member of the European Union even if such country ceases to be a member of the European Union during the term of this Agreement.

1.101 "**Excess Commercialization Costs**" has the meaning set forth in Section 4.10.2.

1.102 "**Excess Development Costs**" has the meaning set forth in Section 3.2.2(a).

1.103 "**Excluded Agreements**" means the agreements set forth on **Schedule 1.103**.

1.104 "**Excluded Collaboration Technology**" has the meaning set forth in Section 6.7.3(a).

1.105 "**Executive Officer**" means, with respect to Alnylam, its Chief Executive Officer, and with respect to Regeneron, its Chief Executive Officer.

1.106 "**Existing Alnylam CMOs**" means each of the Third Party contract manufacturers set forth on **Schedule 1.106** and their respective Affiliates, successors and assigns.[4]

1.107 "**Existing Alnylam In-Licenses**" means the Third Party agreements identified in Section 1 of **Schedule 1.107**,[5] and any Additional Alnylam In-License included within the definition of Existing Alnylam In-Licenses pursuant to Section 6.5.2. For clarity, the Existing Alnylam In-Licenses do not include the Excluded Agreements.

1.108 "**Existing Alnylam Third Party Agreements**" means the agreements identified on **Schedule 1.108**.[6]

1.109 "**Existing Regeneron In-Licenses"** means the Third Party agreements identified on **Schedule 1.109**.[7]

[4] Note to Draft: Schedule 1.106 to include only those Existing Alnylam CMOs under the Master Agreement with respect to the Target Program.

[5] Note to Draft: Schedule 1.107 to include only those Existing Alnylam In-Licenses under the Master Agreement with respect to the Target Program (either Part 1 or Part 2 of the Schedule of Existing Alnylam In-Licenses to the Master Agreement).

[6] Note to Draft: Schedule 1.108 to include only those Existing Alnylam Third Party Agreements under the Master Agreement with respect to the Target Program.

[7] Note to Draft: Schedule 1.109 to include only those Existing Regeneron In-License under the Master Agreement with respect to the Target Program (either Part 1 or Part 2 of the Schedule of Existing Regeneron In-Licenses to the Master Agreement).

1.110 "**Existing Regeneron Third Party Agreements**" means the agreements identified on **Schedule 1.110**.[8]

1.111 "**Expedited Matter**" has the meaning set forth in **Schedule 1**.

1.112 "**Expert**" has the meaning set forth on **Schedule 2**.

1.113 "**Expert Dispute**" has the meaning set forth in Section 2.6.3(b)(v).

1.12 "**Exploit**" means, with respect to a product, to make, have made, import, use, sell, or offer for sale, including to research (including pre-clinical and clinical research), Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of such product. When used as a noun, "**Exploitation**" means the act of Exploiting a product.

1.115 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.116 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.117 "**Field**" means all human diagnostic, prophylactic, and therapeutic uses.

1.118 "**Field Force Cost**" means, for a given Collaboration Product in a country, the product of (a) the number of Lead Party's FTEs conducting Details, performing account management, medical science liaison, medical affairs, nurse trainers or access and reimbursement specialist functions, in each case, in accordance with this Agreement and the Commercialization Plan and Budget and (b) the applicable Field Force FTE Rate(s), in each case, with respect to such country. For the avoidance of doubt, the activities of Third Party contract personnel, shall be charged as Out-of-Pocket Costs and not included in the Field Force Cost.

1.119 "**Field Force FTE Rates**" means, [***].

[8] Note to Draft: Schedule 1.110 to include only those Existing Regeneron Third Party Agreements under the Master Agreement with respect to the Target Program.

1.120 "**Financial Dispute**" means any dispute related to a Party's method of calculation of Development Costs, any element included in the Profit Split or element to determine the Royalties payable, including (a) any apportionment of costs and expenses included therein, including a Party's method of calculation of Other Shared Expenses or Shared Commercial Expenses, (b) with respect to any In-License that is applicable to products other than the Collaboration Products, the allocation of the In-License Payments with respect to such In-License to the Exploitation of Collaboration Products, (c) the budget for any Alnylam Specific Activities Costs to be negotiated by the Parties if Alnylam exercises its Opt-Out Right, as further described in Section 3.5.7(b), and (d) any apportionment of revenues from a Combination Product that contains a Proprietary Unlicensed Component as contemplated in Section 7.1.1.

1.121 "**Financial Expert**" has the meaning set forth in Section 13.5.2(a).

1.122 "**First Commercial Sale**" means, with respect to a Collaboration Product and a country, the first sale by or on behalf of the Lead Party for monetary value for use or consumption by the end user of such Collaboration Product in such country after Regulatory Approval (other than Pricing Approvals) for such Collaboration Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for such Collaboration Product, such as so-called "treatment IND sales," "named patient sales," "early access programs," "temporary use authorization programs," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.123 "**FTE**" means a full time equivalent employee (*i.e.*, one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by a Party (or any of its Affiliates) and assigned to perform specific work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be 1800 hours per year.

1.124 "**FTE Costs and Expenses**" means [***].

1.125 "**Generic Product**" means, with respect to a particular Collaboration Product in a particular country in the Territory, any product that (a) is distributed by a Third Party under a separate Drug Approval Application approved by a Regulatory Authority in reliance, in whole or in part, on the Drug Approval Application for such Collaboration Product in such country (or on safety or efficacy data submitted in support of the Drug Approval Application for such Collaboration Product in such country), including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. § 355(b)(2) and 21 U.S.C. § 355(j), respectively), (ii) in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No. 726/2004 that relies for its content on any such provision) or (iii) in any other country or jurisdiction pursuant to an equivalent of such provisions or (b) is

substitutable under Applicable Law for such Collaboration Product when dispensed without the intervention of a physician or other health care provider with prescribing authority.

1.126 "**Good Manufacturing Practice**" or "**GMP**" means the current good manufacturing practices applicable from time to time to the manufacturing of a Collaboration Product or any intermediate thereof pursuant to Applicable Law.

1.127 "**Healthcare Prescriber**" has the meaning set forth in the definition of "Detail."

1.128 "**In-License**" means (a) any Alnylam In-License, and (b) any Regeneron In-License.

1.129 "**In-License Payments**" means [***].

1.130 "**IND**" means (a) an investigational new drug application filed with the FDA for authorization to commence Clinical Trials and its equivalent in other countries or regulatory jurisdictions, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.131 "**Indemnified Party**" has the meaning set forth in Section 11.2.1.

1.132 "**Indemnifying Party**" has the meaning set forth in Section 11.2.1.

1.133 "**Indirect Costs**" has the meaning set forth in **Schedule 1.165**.

1.134 "**Information**" means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and Materials, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays; and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.135 "**Infringement Action**" has the meaning set forth in Section 8.3.2.

1.136 "**Initiation**" or "**Initiate**" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

1.137 "**Joint Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that are conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, jointly by individuals who are employees, agents or consultants of Alnylam or its Affiliates or its or their Sublicensees, on the one hand, and

individuals who are employees, agents or consultants of Regeneron or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a) (the "**Joint Collaboration Patents**"). Joint Collaboration IP also includes any Joint Collaboration IP (as defined in the Master Agreement) from the Master Agreement with respect to the Target Program. Joint Collaboration IP excludes any Alnylam Background Technology Improvements and any Regeneron Background Technology Improvements.

1.138 "**Joint Collaboration Patents**" has the meaning set forth in the definition of "Joint Collaboration IP."

1.139 "**Joint Commercialization Committee**" or "**JCC**" has the meaning set forth in Section 2.3.1.

1.140 "**Joint Committee**" means each of the Joint Steering Committee, Joint Development Committee, Joint Commercialization Committee, Joint Finance Committee and Joint Manufacturing Committee.

1.141 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 2.2.1.

1.142 "**Joint Finance Committee**" or "**JFC**" has the meaning set forth in Section 2.4.1.

1.143 "**Joint Manufacturing Committee**" or "**JMC**" has the meaning set forth in Section 2.5.1.

1.144 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1.1.

1.145 "**JSC Dispute**" means a dispute that arises with respect to an issue within the jurisdiction of the JSC.

1.146 "**Knowledge**" means, with respect to a Party, the actual knowledge of (i) such Party's internal legal department (including such legal department's intellectual property group), (ii) any employees of such Party who were directly involved in the negotiation of this Agreement with the other Party or who were directly involved in the preparation of such Party's Program Data Package (as defined in the Master Agreement) for the Target Program pursuant to the Master Agreement or (iii) any member of such Party's senior management.

1.147 "**Late Stage Development Plan and Budget**" means, (a) beginning immediately after the Phase 2 Completion Date through First Commercial Sale in the first Major Market Country, the development plan setting forth in reasonable detail (i) the comprehensive plan for the Development of the Collaboration Products for Commercialization in the Territory during such

period, including the applicable Development Phase Budget, and (ii) the rolling [***] plan of specific Development activities to be performed with respect to the Collaboration Products and the anticipated timeline and Development Budget, or (b) beginning with the First Commercial Sale in the first Major Market Country, the rolling [***] plan of specific Development activities to be performed with respect to the Collaboration Products and the anticipated timeline and Post-Approval Development Budget. Such plan shall allocate responsibility for such Development activities between the Parties; provided, that the Parties anticipate that the Lead Party shall be primarily responsible for conducting all Development activities set forth in the Late Stage Development Plan and Budget; provided further that if Regeneron is the Lead Party, Alnylam shall be responsible for the Alnylam Specific Activities set forth in the Late Stage Development Plan and Budget. The initial Late Stage Development Plan and Budget is expected to include any ongoing Development activities set forth in the Phase 2 Development Plan and Budget that have not been completed as of the Phase 2 Completion Date. [***]

1.148 "**Late Stage Development Supply Requirements**" means the quantities of Collaboration Products (and placebo) that are reasonably required by either Party to perform its Development activities under the Late Stage Development Plan and Budget.

1.149 "**Late Stage Supply Requirements**" means the Late Stage Development Supply Requirements and Commercial Supply Requirements.

1.150 "**Lead Party**" means [_____][9] unless and until such Party exercises its Opt-Out Right, in which case [_____][10] becomes the Lead Party from and after the date of such exercise.

1.151 "**Lead Party Indemnitees**" has the meaning set forth in **Schedule 12.6(B)**.

1.152 "**Lead Party Quarterly Expenses**" has the meaning set forth in **Schedule 7.1.1**.

1.153 "**Lead Party Termination Core Technology Know-How**" has the meaning set forth in **Schedule 12.6(B)**.

1.154 "**Lead Party Termination Core Technology Patents**" has the meaning set forth in **Schedule 12.6(B)**.

1.155 "**Lead Party Termination Product-Specific Know-How**" has the meaning set forth in **Schedule 12.6(B)**.

[9] Note to Draft: Insert the name of the Party (either Alnylam or Regeneron) that is designated the Lead Party for this Agreement in accordance with the Master Agreement.

[10] Note to Draft: Insert the name of the Party (either Regeneron or Alnylam) that is not designated the Lead Party for this Agreement in accordance with the Master Agreement.

1.156 "**Lead Party Termination Product-Specific Patents**" has the meaning set forth in **Schedule 12.6(B)**.

1.157 "**Lead Patent Party**" means the Lead Party (which, for clarity, may be the New Lead Party if the initial Lead Party exercises its Opt-Out Right).

1.158 "**Legal Dispute**" means any dispute related to a Party's alleged material breach of this Agreement or the validity, breach, termination or interpretation of this Agreement, or intellectual property-related disputes.

1.159 "**License Agreement**" means (i) any License Agreement (as defined in the Master Agreement) that is entered into by the Parties (or their respective Affiliates) pursuant to the Master Agreement and [***].

1.160 [***]

1.161 "**MAA**" has the meaning set forth in the definition of "Drug Approval Application."

1.162 "**Major Market Country**" means each of the United States, Japan, France, Germany, Italy, the United Kingdom and Spain.

1.163 "**Major Regulatory Filings**" has the meaning set forth in Section 3.6.1(c)(i).

1.164 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, assembling, shipping, and holding of any Collaboration Product, or any intermediate thereof, and any placebo, as the case may be (including any devices or other delivery technologies that are packaged or distributed with a Collaboration Product), including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control, and management of any Third Party contractors conducting such activities.

1.165 "**Manufacturing Cost**" has the meaning set forth on **Schedule 1.165**.

1.166 "**Manufacturing Plan**" means, with respect to a Collaboration Product, a manufacturing plan setting forth process and technology selection, process improvements and all related process development activities that impact Manufacturing of a Collaboration Product, including a plan for a second source manufacturer for Collaboration Products and shall be designed to ensure reasonably adequate supply of the Early Stage Supply Requirements and the Late Stage

Supply Requirements. Each Manufacturing Plan will further set forth the estimated capacity requirements to meet forecasted demand over an ensuing period of at least [***] Calendar Years. The initial Manufacturing Plan will cover at least the initial expected Early Stage Supply Requirements for Collaboration Products.

1.167 "**Manufacturing Process**" means the then-current process for the Manufacture of Collaboration Products.

1.168 "**Manufacturing Technology Transfer**" has the meaning set forth in Section 5.3.3.

1.169 "**Manufacturing Technology Transfer Costs**" means the FTE Costs and Expenses and Out-of-Pocket Costs incurred by either Party in connection with a Manufacturing Technology Transfer pursuant to Section 5.2.2, Section 5.3.3(a) or Section 5.3.3(b). Manufacturing Technology Transfer Costs do not include the costs with respect to any Manufacturing Technology Transfer requested by Regeneron due to a Material Supply Failure (which costs, for clarity, will be borne by Alnylam), unless such Material Supply Failure is caused by or results, in whole or part, from an event of force majeure (as described in Section 13.1 of this Agreement) that applies to Alnylam, its Affiliate or its Third Party contract manufacturer(s), in which case, such costs are Manufacturing Technology Transfer Costs.

1.170 "**Material Supply Failure**" means, [***], with respect to a Collaboration Product, [***] failure to deliver [***] at least [***] of the quantity of Collaboration Product in accordance with the specifications as ordered in a [***] period in accordance with the forecasting and ordering procedures in the Supply Agreement [***]. The Parties acknowledge that as of the Effective Date no Manufacturing Process has been developed, and no [***] has been selected, for the Manufacture of Collaboration Product at scale. Therefore, the Parties may discuss in good faith reasonable modifications to the quantitative standard for Material Supply Failure in this definition for inclusion in the Supply Agreement, based on forecast, lead time, the Lead Party's supply requirements, [***] manufacturing slot availability, batch/order size and other relevant considerations known.

1.171 "**Materials**" means all tangible compositions of matter, devices, articles of manufacture, assays, animal models, biological, chemical, or physical materials, and other similar materials, including cell lines and animal models; provided that "Materials" excludes Collaboration Products.

1.172 "**MicroRNA**" or "**miRNA**" means a structurally defined functional RNA molecule usually between nineteen (19) and twenty-five (25) nucleotides in length, which is derived from an endogenous, genetically-encoded non-coding RNA which is predicted to be processed into a hairpin RNA structure that is a substrate for the double-stranded RNA-specific ribonuclease drosha and subsequently is predicted to serve as a substrate for the enzyme dicer, a member of the RNase III enzyme family.

1.173 "**MicroRNA Mimic**" means a single-stranded or double-stranded oligonucleotide with the same or substantially similar base composition and sequence (including chemically modified bases) as a particular natural miRNA and which is designed to mimic the activity of such miRNA. For clarity, MicroRNA Mimic excludes a double-stranded oligonucleotide which functions or is designed to function as an siRNA.

1.174 "**Minimum Internal Manufacturing Requirements**" means if either Alnylam or Regeneron, as applicable, desires to Manufacture Collaboration Product directly (either itself or through an Affiliate) rather than through a Third Party contract manufacturer, that such Party (or its Affiliate, as applicable) satisfies all of the following:

1.174.1 [***]

1.174.2 the quality, compliance and reliability with respect to the Manufacture of Collaboration Product directly by such Party (or its Affiliate) is reasonably expected to be comparable to or better than the quality, compliance and reliability with respect to the Manufacture of Collaboration Product by other Third Party contract manufacturers who have experience manufacturing siRNAs;

1.174.3 the facility at which such Party (or its Affiliate) will Manufacture Collaboration Product satisfies industry standards as demonstrated by the results of a reasonably recent qualification audit; and

1.174.4 the facility at which such Party (or its Affiliate) will Manufacture Collaboration Product will be timely validated, fully operational and have sufficient capacity to Manufacture the Early Stage Supply Requirements or Late Stage Supply Requirements, as applicable.

1.175 "**NDA**" has the meaning set forth in the definition of "Drug Approval Application."

1.176 "**Net Sales**" means, [***]

1.177 "**New External Program**" has the meaning set forth in Section 3.1.15.

1.178 "**New Lead Party**" has the meaning set forth in **Schedule 3.5.7(a)**.

1.179 "**New Program Permitted Dual Sequence Uses**" has the meaning set forth in Section 3.1.15.

1.180 "**Non-Acquiring Party**" has the meaning set forth in Section 6.7.2(a).

1.181 "**Non-Approval Trials**" means any surveys, registries and Clinical Trials not intended to gain Regulatory Approval or any additional labeled indications, excluding any open label extension studies of the Collaboration Products.

1.182 "**Non-Breaching Party**" has the meaning set forth in Section 12.2.

1.183 "**Non-Relevant Organ Delivery Technology**" means [***].

1.184 "**Ongoing Candidate Discovery Activities**" has the meaning set forth in the definition of "Pre-Clinical Plan and Budget."

1.185 "**Opt-Out Date**" has the meaning set forth in Section 3.5.1.

1.186 "**Opt-Out Development Costs**" has the meaning set forth in Section 3.5.7(g).

1.187 "**Opt-Out Notice**" has the meaning set forth in Section 3.5.1.

1.188 "**Opt-Out Party**" had the meaning set forth in Section 3.5.7.

1.189 "**Opt-Out Right**" has the meaning set forth in Section 3.5.1.

1.190 "**Opt-Out Transition Agreement**" has the meaning set forth in **Schedule 3.5.7(a)**.

1.191 "**Opt-Out Transition Costs**" has the meaning set forth in **Schedule 3.5.7(a)**.

1.192 "**Option Threshold**" means, [***].

1.193 "**Other Shared Expenses**" means, with respect to a Collaboration Product, (a) Shared Claims and Shared Damages, (b) those costs and expenses incurred by a Party that are specifically referred to in Section 3.6.2, Section 5.5.1, Section 8.2.1, Section 8.2.6, Section 8.3.2, Section 8.5.6, Section 8.6.4, Section 8.7.1, Section 11.1.3, Section 11.2.3 and Section 11.2.5 and (c) other costs agreed between the Parties in writing to be included therein, to the extent that such costs and expenses do not include any costs and expenses included in Development Costs or Shared Commercial Expenses. If any of the foregoing costs benefit both Collaboration Product(s) and other products or activities of a Party (for example, if an In-License is not exclusively of benefit to Collaboration Products), then the applicable Party incurring such costs shall apportion such costs in a manner that fairly and reasonably reflects the benefit to the Collaboration Products and the other products or activities of such Party. Each Party shall disclose both the total costs incurred and the apportionment in the information reported under Section 7.1.3(d) for review by the other Party. At the request of the other Party, the Party making the apportionment shall provide additional reasonable supporting documentation and make its personnel reasonably available to answer questions. Any dispute regarding such apportionment shall be a Financial Dispute.

1.194 "**Out-of-Pocket Costs**" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the paying Party's Accounting Standards) by either Party or its Affiliates in connection with activities under this Agreement, excluding FTE Costs and Expenses.

1.195 "**Participating Party**" means, at any time, the Party that is not the Lead Party at such time.

1.196 "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.197 "**Patent Rights**" means (a) all issued patents (including any extensions, restorations by any existing or future extension or registration mechanism (including patent term adjustments, patent term extensions, supplemental protection certificates or the equivalent thereof), substitutions, confirmations, re-registrations, re-examinations, and patents of addition); (b) patent applications (including all provisional applications, substitutions, requests for continuation, continuations, continuations-in-part, divisionals and renewals); (c) inventor's certificates; and (d) all equivalents of the foregoing in any country of the world.

1.198 "**Permitted Alnylam Outside Product**" means [***].

1.199 [***]

1.200 "**Permitted Claim Scope**" means [***].

1.201 "**Permitted Commercialization Overrun**" has the meaning set forth in Section 4.10.2.

1.202 "**Permitted Competing Product**" means any [(a)]Competing Products Directed to the Target pursuant to the exception to exclusivity set forth in Section 6.7.1(a)(A)[, and (b) Competing Products set forth on **Schedule 1.202**].[11]

1.203 "**Permitted Development Overrun**" has the meaning set forth in Section 3.2.2(a).

1.204 "**Permitted Dual Sequence**" means [***].

1.205 "**Permitted Dual Sequence Uses**" means, with respect to any Permitted Dual Sequence, [***], as applicable.

1.206 "**Permitted Regeneron Outside Product**" means [***].

[11] Note to Draft: Include this bracketed language and this schedule only if the Target was a CNS Target under the Master Agreement and there were Competing Products Directed to the Target that were permitted with respect to the Target pursuant to subsection (C) or (D) of Section 5.7.1(a) of the Master Agreement. If included, the schedule should include the applicable exceptions.

1.207 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.208 "**Phase 1 Clinical Trial**" means a human clinical trial of a Collaboration Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, or a similar clinical study prescribed by the applicable Regulatory Authorities, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(a), as amended.

1.209 "**Phase 1 Completion Date**" means the date the Clinical Trial results (e.g., key results memo) from the Phase 1 Clinical Trial conducted under the Phase 1 Development Plan and Budget that are sufficient to support the Initiation of a Phase 2 Clinical Trial for the first Collaboration Product are made available to the JSC; provided that the foregoing shall not limit in any way an Opt-Out Party's obligations under Section 3.5.7.

1.210 "**Phase 1 Development Plan and Budget**" means, for Development activities beginning immediately after acceptance by the applicable Regulatory Authority in a Major Market Country (or the EMA pursuant to the centralized approval procedure, or in any other country identified in the Pre-Clinical Plan and Budget in which the Parties intend to file an IND for a Collaboration Product) of the IND for the first Collaboration Product and continuing up to completion of the Phase 1 Clinical Trial(s) for the first Collaboration Product, the development plan setting forth in reasonable detail (a) the comprehensive plan for the Development of the Collaboration Products in the Territory during such period, including the applicable Development Phase Budget, and (b) the rolling [***] plan of specific Development activities to be performed with respect to the Collaboration Products and the anticipated timeline and Development Budget. The Parties anticipate that Lead Party shall be primarily responsible for conducting such Phase 1 Clinical Trials; provided that if Regeneron is the Lead Party, Alnylam shall be responsible for the Alnylam Specific Activities set forth in the Phase 1 Development Plan and Budget (as well as the Manufacture and supply of Early Stage Supply Requirements). For clarity, the activities under the Phase 1 Development Plan and Budget may continue even if the Phase 2 Development Plan and Budget has commenced. [***]

1.211 "**Phase 2 Clinical Trial**" means a human clinical trial of a Collaboration Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, or a similar clinical study prescribed by the applicable Regulatory Authorities, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(b), as amended.

1.212 "**Phase 2 Completion Date**" means the date that the Clinical Trial results (e.g., key results memo) from the Phase 2 Clinical Trial conducted under the Phase 2 Development Plan and Budget that are sufficient to support the Initiation of a Registration Enabling Trial for the first Collaboration Product are made available to the JSC; provided that the foregoing shall not limit in any way an Opt-Out Party's obligations under Section 3.5.7.

1.213 "**Phase 2 Development Plan and Budget**" means, for Development activities beginning immediately after the Phase 1 Completion Date and continuing up to the completion of the Phase 2 Clinical Trial(s) for the first Collaboration Product, the development plan setting forth in reasonable detail (a) the comprehensive plan for the Development of the Collaboration Products in the Territory during such period, including the applicable Development Phase Budget, and (b) the rolling [***] plan of specific Development activities to be performed with respect to the Collaboration Products and the anticipated timeline and Development Budget, which plan shall allocate responsibility for such Development activities between the Parties; provided, that the Parties anticipate that the Lead Party shall be primarily responsible for all Development activities set forth in the Phase 2 Development Plan and Budget; provided that if Regeneron is the Lead Party, Alnylam shall be responsible for the Alnylam Specific Activities set forth in the Phase 2 Development Plan and Budget (as well as the Manufacture and supply of Early Stage Supply Requirements). For clarity, the activities under the Phase 2 Development Plan and Budget may continue even if the Late Stage Development Plan and Budget has commenced. [***]

1.214 "**Phase 3 Clinical Trial**" means a human clinical trial of a Collaboration Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use and to determine warnings, precautions, and adverse reactions that are associated with such Collaboration Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Collaboration Product, including all tests and studies that are required by the FDA, pursuant to Applicable Law or otherwise.

1.215 "**Post-Approval Development Budget**" has the meaning set forth in Section 3.1.7(b).

1.216 "**Post-Termination Payments**" has the meaning set forth in **Schedule 12.6(B)**.

1.217 "**Pre-Clinical Plan and Budget**" means, for Development activities to support an IND filing (following lead candidate identification) for the first Collaboration Product through the acceptance by the applicable Regulatory Authority in a Major Market Country (or the EMA pursuant

to the centralized approval procedure, or in any other country identified in the Pre-Clinical Plan and Budget in which the Parties intend to file an IND for a Collaboration Product) of the first IND for such Collaboration Product, the development plan setting forth in reasonable detail (x) the comprehensive plan for the Development of the Collaboration Products in the Territory during such period, including the applicable Development Phase Budget, and (y) the rolling [***] plan of specific Development activities to be performed with respect to the Collaboration Products (including preclinical Development and Manufacturing to support IND filings for the Collaboration Products) and the anticipated timeline and Development Budget. Such plan shall allocate responsibility for such Development activities primarily to the Lead Party; provided that if Regeneron is the Lead Party, Alnylam shall be responsible for the Alnylam Specific Activities set forth in the Pre-Clinical Plan and Budget (as well as the Manufacture and supply of Early Stage Supply Requirements for such studies). The initial Pre-Clinical Plan and Budget is expected to include any ongoing Development activities under the Candidate Discovery Plan (as defined in the Master Agreement) for the Target Program that have not been completed as of the Effective Date (the "**Ongoing Candidate Discovery Development Activities**"); provided that the Party that was allocated the applicable Ongoing Candidate Discovery Development Activity under such Candidate Discovery Plan shall be responsible for the continued performance of such activities under the Pre-Clinical Plan and Budget. For clarity, the activities under the Pre-Clinical Plan and Budget may continue even if the Phase 1 Development Plan and Budget has commenced. In no event shall the Pre-Clinical Plan and Budget include any activities for the general development of the Alnylam siRNA Platform.

1.218 "**Pre-Existing Affiliates**" has the meaning set forth in Section 6.7.2(e).

1.219 "**Pricing Approval**" means such approval, agreement, determination or governmental decision establishing prices for a Collaboration Product that can be charged to consumers and will be reimbursed by Regulatory Authorities in countries where Regulatory Authorities of such countries approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.220 "**Product Labeling**" means, with respect to a Collaboration Product in a country in the Territory, (a) the Regulatory Authority approved full prescribing information for such Collaboration Product for such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Collaboration Product in such country.

1.221 "**Product Regulatory Documentation**" has the meaning set forth in Section 9.1.

1.222 "**Product-Related In-License**" means a license or other similar agreement with a Third Party (other than the Existing Alnylam In-Licenses and the Existing Regeneron In-Licenses)

to license or obtain any similar right or interest in any (a) Information necessary or reasonably useful to perform any activities under a Development Plan and Budget or to achieve the objectives thereof or to Exploit any Collaboration Product or (b) Patent Right that Covers any Collaboration Product or the Exploitation thereof.

1.223 "**Product-Related IP**" has the meaning set forth in Section 8.3.2.

1.224 "**Product-Related Patents**" has the meaning set forth in Section 8.2.1(a).

1.225 "**Product-Specific Factors**" means [***].

1.226 "**Product-Specific Information**" has the meaning set forth in Section 9.1.

1.227 "**Product-Specific In-License**" means a Product-Related In-License for Information that is primarily related to, or Patent Rights that primarily claim, Product-Specific Factors.

1.228 "**Product Trademarks and Domain Names**" means the Trademark(s) and any domain names to be used by the Lead Party or its Affiliates or Sublicensees for the Commercialization of Collaboration Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

1.229 "**Profit Payment Report**" means the consolidated report prepared by the Lead Party each Calendar Quarter (based on information reported under Section 7.1.3) setting forth in reasonable detail, for each Major Market Country, and in the aggregate, worldwide as a whole, (a) Net Sales, Cost of Goods Sold, and Shared Commercial Expenses invoiced or incurred by each Party for such Calendar Quarter, (b) Third Party Transaction Proceeds received by the Lead Party for such Calendar Quarter, (c) Other Shared Expenses incurred by each Party for such Calendar Quarter, and (d) the Quarterly Profit True-Up, and the component items and calculations in determining such Quarterly Profit True-Up, calculated in accordance with **Schedule 7.1.1**. If an item is included in one Profit Payment Report, in no event shall the same item be included in a subsequent Profit Payment Report.

1.230 "**Profit Split**" has the meaning set forth in **Schedule 7.1.1**.

1.231 "**Profits**" has the meaning set forth in **Schedule 7.1.1**.

1.232 "**Promotional Materials**" means, with respect to each Collaboration Product and country in which such Collaboration Product is or will be sold, promotional, advertising, communication and educational materials relating to such Collaboration Product for use in connection with the marketing, promotion and sale of such Collaboration Product in such country,

and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.233 [“**Proof of Principle Criteria**” means the criteria to be mutually agreed to by the Parties prior to the commencement of the first Phase 1 Clinical Trial for the Relevant Organ Product, as described in more detail in the Master Agreement.

1.234 “**Proof of Principle Study**” means a Clinical Trial conducted under this Agreement that is designed to meet the Proof of Principle Criteria and identified by the Lead Party to the JSC pursuant to Section 3.1.10 hereof.][12]

1.235 “**Proposal**” has the meaning set forth in **Schedule 1**.

1.236 “**Proprietary Unlicensed Component**” means, with respect to a given Party, an Unlicensed Component that is (a) proprietary to such Party (or its Affiliate) or (b) otherwise controlled (through license or otherwise) by such Party (or its Affiliate).

1.237 “**Proprietary Unlicensed Component Non-Collaboration Development Costs**” means, [***].

1.238 “**Quality Agreement**” has the meaning set forth in Section 5.2.2.

1.239 “**Quarterly Development True-Up**” has the meaning set forth in **Schedule 7.1.1**.

1.240 “**Quarterly Profit True-Up**” has the meaning set forth in **Schedule 7.1.1**.

1.241 “**Recoupment Amount**” means, with respect to a Party, subject to Section 7.1.4(b) and Section 7.2.6(c), an amount equal to the sum of the following: (a) [***] of the Excess Development Costs incurred by such Party in the performance of any Development activities for Collaboration Products that are necessary or reasonably useful to successfully achieve the objectives contemplated by the applicable Development Plan and Budget, (b) [***] of the Excess Commercialization Costs incurred by such Party and (c) [***] of the Opt-Out Development Costs incurred by such Party; provided, that if a Party exercises its Opt-Out Right, no Excess Development Costs or Excess Commercialization Costs incurred by such Party after the corresponding Opt-Out Date shall be included such Party’s Recoupment Amount.

[12] Note to Draft: Definitions of Proof of Principle Criteria and Proof of Principle Study will be included only if the Target is a CNS Target.

1.242 "**Recoupment Balance**" means, with respect to a Party, subject to Section 7.1.4(b) and Section 7.2.6(c), an amount equal to the Recoupment Amount with respect to such Party less the sum of (a) any reductions in Quarterly Profit True-Up payments by such Party pursuant to Section 7.1.4(a)(i), (b) any increases in Quarterly Profit True-Up payments by the other Party pursuant to Section 7.1.4(a)(ii), (c) any reductions in Royalty payments by such Party pursuant to Section 7.2.6(a) and (d) any increases in Royalty payments by the other Party pursuant to Section 7.2.6(b).

1.243 "**Regeneron**" has the meaning set forth in the preamble hereto.

1.244 "**Regeneron Background Technology**" means (a) Information that is necessary or reasonably useful to Exploit any Collaboration Product and (b) Patent Rights that Cover any Collaboration Product or the Exploitation of any Collaboration Product, in each case, ((a) and (b)), that are Controlled by Regeneron or its Affiliates during the Term, but excluding Regeneron Collaboration IP and Regeneron's interest in the Joint Collaboration IP. [***]

1.245 "**Regeneron Background Technology Improvements**" means any developments, enhancements, modifications or other improvements to, or progeny, mutants, fragments, or derivatives of, (x) the Regeneron Background Technology or [***], that (a) are made by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement, and (b) with respect to any of the foregoing constituting (i) Information, are not specifically and solely related to any Product-Specific Factor and (ii) Patent Rights, do not include any claim the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.246 "**Regeneron Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that is conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by individuals who are employees, agents or consultants of Regeneron or its Affiliates or its or their Sublicensees, in each case, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a). Regeneron Collaboration IP excludes Regeneron's interest in Joint Collaboration IP and any Alnylam Background Technology Improvements. Patent Rights constituting Regeneron Collaboration IP are either Regeneron Core Technology Patents or Regeneron Product-Specific Patents, as the case may be.

1.247 "**Regeneron Core Technology Know-How**" means Regeneron Know-How other than Regeneron Product-Specific Know-How.

1.248 "**Regeneron Core Technology Patents**" means Regeneron Patents other than Regeneron Product-Specific Patents.

1.249 "**Regeneron In-License**" means any (a) Existing Regeneron In-License, (b) Product-Specific In-License between Regeneron (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent that such agreement is designated as a Regeneron In-License pursuant to Section 6.5.1(a) or (c) Core Technology In-License between Regeneron (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent such agreement is designated as a Regeneron In-License pursuant to Section 6.5.1(c) or Section 6.5.1(d). In the event that a given Product-Specific In-License (as defined in the Master Agreement) or Core Technology In-License (as defined in the Master Agreement) between Regeneron (or its Affiliates) and a Third Party was designated to be a Regeneron In-License (as defined in the Master Agreement) for the Target Program pursuant to the Master Agreement, then such agreement shall also be a Regeneron-In License for this Agreement (as a Product-Specific In-License or Core Technology In-License, as applicable, but shall not be an Existing Regeneron In-License).

1.250 "**Regeneron Indemnitees**" has the meaning set forth in Section 11.1.1.

1.251 "**Regeneron Internal Manufacturing Costs**" has the meaning set forth in the definition of "Minimum Internal Manufacturing Requirements".

1.252 "**Regeneron Know-How**" means (a) the Information included in the Regeneron Collaboration IP; (b) Regeneron's interest in the Information included in the Joint Collaboration IP; and (c) the Information included in any Regeneron Background Technology or in any Regeneron Background Technology Improvements that is not in the public domain or otherwise generally known.

1.253 "**Regeneron Managed Patents**" has the meaning set forth in Section 10.3.3.

1.254 "**Regeneron Manufacturing Technology**" means Regeneron Technology relating to the Manufacturing Process of a Collaboration Product that is Controlled by Regeneron or its Affiliates during the Term.

1.255 "**Regeneron Mice**" means Regeneron's proprietary, genetically engineered mice, and any progeny of such mice (including cross-bred progeny resulting from producing a genetically engineered mouse by breeding or by using any portion of any of Regeneron's proprietary genetically engineered mice) or other mice derived therefrom.

1.256 "**Regeneron Patents**" means (a) the Patent Rights included in the Regeneron Collaboration IP; (b) Regeneron's interest in the Joint Collaboration Patents; and (c) the Patent

Rights included in any Regeneron Background Technology or in any Regeneron Background Technology Improvements.

1.257 "**Regeneron Product-Specific Know-How**" means Regeneron Know-How that is specifically and solely related to Product-Specific Factors.

1.258 "**Regeneron Product-Specific Patents**" means the Regeneron Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor, including those Patent Rights set forth on **Schedule 1.258**.

1.259 "**Regeneron Technology**" means, collectively, Regeneron Know-How and Regeneron Patents.

1.260 "**Regeneron Termination Core Technology Know-How**" means Regeneron Termination Know-How other than Regeneron Termination Product-Specific Know-How.

1.261 "**Regeneron Termination Core Technology Patents**" means Regeneron Termination Patents other than Regeneron Termination Product-Specific Patents.

1.262 "**Regeneron Termination Know-How**" means any Regeneron Know-How existing as of the effective date of termination of this Agreement that (i) is not in the public domain or otherwise generally known and (ii) is necessary or reasonably useful to further Exploit a Terminated Product (A) as such Terminated Product exists as of the effective date of termination of this Agreement or (B) based on the Development Plan and Budget in effect as of the effective date of termination of this Agreement.

1.263 "**Regeneron Termination Patents**" means (a) any Regeneron Patents existing as of the effective date of termination of this Agreement that are necessary or reasonably useful to Exploit a Terminated Product, (i) as such Terminated Product exists as of the effective date of termination of this Agreement or (ii) based on the Development Plan and Budget in effect as of the effective date of termination of this Agreement, and (b) any Patent Rights that claim priority to any Regeneron Patents in clause (a).

1.264 "**Regeneron Termination Product-Specific Know-How**" means Regeneron Termination Know-How that is specifically and solely related to Product-Specific Factors.

1.265 "**Regeneron Termination Product-Specific Patents**" means the Regeneron Termination Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.266 "**Registration Enabling Trial**" means a human clinical trial (whether or not designated a Phase 3 Clinical Trial) of a Collaboration Product (a) the results of which, together

with prior data and information concerning such Collaboration Product, are intended at the time such human clinical trial is Initiated to establish that such Collaboration Product is safe and effective for its intended use; and (b) that forms the basis (alone or with one or more additional Registration Enabling Trials) of an effectiveness claim in support of a Regulatory Approval for such Collaboration Product, in each case ((a) and (b)), as acknowledged in writing by the FDA for any human clinical trial that does not meet the criteria for a Phase 3 Clinical Trial at the time such human clinical trial is Initiated.

1.267 "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, or market a Collaboration Product in such country, including, where applicable, (a) Pricing Approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) labeling approval.

1.268 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Collaboration Product in the Territory.

1.269 "**Regulatory Documentation**" means all (a) applications (including all INDs and Drug Approval Applications and other Major Regulatory Filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files.

1.270 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Collaboration Product other than Patent Rights.

1.271 "**Relevant Organ**" means [_____][13].

1.272 "**Relevant Organ Product**" means any product containing siRNA that has been specifically engineered or selected to be Directed to the Target as expressed in the Relevant Organ; provided that such product shall still be a "Relevant Organ Product" even if such product is also Directed to such Target as expressed in another organ(s) in the body.

[13] Note to Draft: Insert the definition of "Liver" or "CNS" from the Master Agreement, as applicable. In the event that "Eye" (as defined in the Master Agreement) or any other organs are to be included in this Agreement pursuant to Section 5.7.1(a)(C)(b) of the Master Agreement, then this Agreement will need to be amended to include the Eye or such other organs, as applicable, as set forth in Section 5.7.1(a)(C)(b) of the Master Agreement.

1.273 "**Requesting Party**" has the meaning set forth in Section 3.3.

1.274 "**Royalties**" has the meaning set forth in Section 7.2.1.

1.275 "**Royalty Term**" means, with respect to a Collaboration Product and a country, the period commencing on the date of the First Commercial Sale of such Collaboration Product in such country and continuing until the latest of (a) the expiration of the last Valid Claim in such country of an Alnylam Patent (other than any Alnylam Core Technology Patent that is excluded for purposes of the Royalty Term pursuant to Section 8.3.3), Joint Collaboration Patent or Regeneron Patent (other than any Regeneron Core Technology Patent that is excluded for purposes of the Royalty Term pursuant to Section 8.3.4) that Covers such Collaboration Product, provided that the use or sale of such Collaboration Product by the Lead Party (or its Affiliate or Sublicensee) in such country infringes such Valid Claim in such country (notwithstanding any license or ownership interest therein), (b) expiration of Regulatory Exclusivity for the such Collaboration Product in such country and (c) the [***] anniversary of the First Commercial Sale of such Collaboration Product in such country.

1.276 "**Rules**" has the meaning set forth in **Schedule 1**.

1.277 "**Shared Claim**" has the meaning set forth in Section 11.1.3.

1.278 "**Shared Commercial Expenses**" means the sum of the following items, in each case to the extent directly attributable to Commercialization of Collaboration Products worldwide in accordance with Commercialization Plan and Budget, whether incurred prior to or after First Commercial Sale of a Collaboration Product except as otherwise set forth in this Agreement, and to the extent that such items do not include any costs included in Development Costs:

1.278.1 Field Force Costs;

1.278.2 Out-of-Pocket Costs related to (a) the marketing, advertising or promotion of Collaboration Products worldwide (including, pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia and Promotional Materials for the Collaboration Product), (b) market research for Collaboration Products worldwide and (c) the preparation of training and communication materials for Collaboration Products worldwide;

1.278.3 Out-of-Pocket Costs related to [***] for Collaboration Products worldwide, including the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies

to centers or disposal of clinical supplies, in each case, to the extent not already included in the Cost of Goods Sold for such Collaboration Product;

1.278.4 Out-of-Pocket Costs related to [***] and the maintenance of all Regulatory Approvals directly related to the Commercialization of Collaboration Products;

1.278.5 Commercial Overhead Charge;

1.278.6 Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Regulatory Approval of indications and line extensions;

1.278.7 any In-License Payments to the extent attributable to the Commercialization of Collaboration Products (to the extent not otherwise included in Development Costs);

1.278.8 Manufacturing Costs for Commercial Supply Requirements Manufactured prior to the First Commercial Sale; and

1.278.9 any other costs or expenses directly related to the Commercialization of a Collaboration Product and not included in clauses 1.278.1 through clauses 1.278.8 above and specifically identified and included in the Commercialization Plan and Budget, or included as Shared Commercial Expenses under this Agreement.

If any of the foregoing costs benefit both Collaboration Product(s) and other products or activities of a Party (for example, if an In-License is not exclusively of benefit to Collaboration Products), then the applicable Party incurring such costs shall apportion such costs in a manner that fairly and reasonably reflects the benefit to the Collaboration Products and the other products or activities of such Party. Each Party shall disclose both the total costs incurred and the apportionment in the information reported under Section 7.1.3(d) for review by the other Party. At the request of the other Party, the Party making the apportionment shall provide additional reasonable supporting documentation and make its personnel reasonably available to answer questions. Any dispute regarding such apportionment shall be a Financial Dispute. In no event shall the same costs be included more than once in Shared Commercial Expenses under this Agreement, even if such costs are of benefit to multiple Collaboration Products, provided that the applicable Collaboration Products under or in connection with this Agreement benefitted by such Shared Commercial Expenses may be taken into consideration with respect to such apportionment.

1.279 "**Shared Damage**s" has the meaning set forth in Section 11.1.3.

1.280 "**Shared Facility**" has the meaning set forth in **Schedule 1.165**.

1.281 "**siRNA**" means an oligonucleotide composition of native or chemically modified RNA that targets a gene through activation of the RNA interference pathway, and that is not a MicroRNA, MicroRNA antagonist or MicroRNA Mimic.

1.282 "**Sublicensed Party**" has the meaning set forth in Section 6.5.4.

1.283 "**Sublicensee**" means a Third Party that is granted, in accordance with this Agreement, a (sub)license by a Party or its Affiliates to intellectual property licensed under this Agreement by such Party or its Affiliates to, or to such Party and its Affiliates by, the other Party or its Affiliates, to Develop or Commercialize a Collaboration Product.

1.284 "**Sublicensor Party**" has the meaning set forth in Section 6.5.4.

1.285 "**Supply Agreement**" has the meaning set forth in Section 5.2.2.

1.286 "**Supply Price**" has the meaning set forth in Section 5.2.2.

1.287 "**Target**" means the target identified on **Schedule 1.287**.[14]

1.288 "**Term**" has the meaning set forth in Section 12.1.

1.289 "**Terminated Product**" means any Collaboration Product that is the subject of Development or Commercialization by or on behalf of the Lead Party in the Territory as of the effective date of termination of this Agreement, but excluding [***].

1.290 "**Termination Transition Agreement**" has the meaning set forth in **Schedule 12.6(B)**.

1.291 "**Territory**" means the entire world.

1.292 "**Third Party**" means any Person other than Alnylam, Regeneron and their respective Affiliates.

1.293 "**Third Party Acquisition**" has the meaning set forth in Section 6.7.2(a).

1.294 "**Third Party Infringement Action**" has the meaning set forth in Section 8.6.1.

1.295 "**Third Party Manufacturing Costs**" has the meaning set forth in the definition of "Minimum Internal Manufacturing Requirements".

[14] Note to Draft: Add the identity of the Target under this Agreement on **Schedule 1.285** at the time of execution of this Agreement.

1.296 "**Third Party Provider**" has the meaning set forth in Section 3.1.9.

1.297 "**Third Party Transaction**" means any transaction pursuant to which the Lead Party or its Affiliates grants a license, sells or otherwise grants or transfers, including by option, to any Third Party (other than in connection with (i) a Change of Control (provided, however that any such transaction shall be considered a "Third Party Transaction" where, as of the consummation of such transaction, the Collaboration Product(s) which are the subject matter of this Agreement constitutes a majority of the assets of such Party) or (ii) a subcontract as permitted pursuant to Section 3.1.9) rights in or to, including any rights to further Develop or Commercialize, one or more Collaboration Products.

1.298 "**Third Party Transaction Proceeds**" means, with respect to a Third Party Transaction, any and all proceeds received by the Lead Party or any of its Affiliates from Third Parties in respect of such Third Party Transaction, including (a) upfront and milestone payments; (b) royalties, sales milestones, profit share and other payments based on the sales of a Collaboration Product; (c) the fair market value of any equity or debt securities issued in respect of such Third Party Transaction to such Party or its Affiliates that exceeds any amount paid by such Party or its Affiliates for such securities; (d) the amount by which any amount paid by a Third Party to such Party or its Affiliates for any equity or debt securities issued to such Third Party in respect of such Third Party Transaction exceeds the fair market value of such securities; (e) the amount by which the transfer price for any Collaboration Product paid by a Third Party to such Party or its Affiliates exceeds the actual Manufacturing Costs for such Collaboration Product; (f) the fair market value of any other form of consideration paid to, or received by or otherwise recognized by such Party or its Affiliates by or from a Third Party in connection with such Third Party Transaction as reasonably agreed by the Parties; but excluding any amounts received by the Lead Party or any of its Affiliates at any time after a Party exercises its Opt-Out Right, as (i) reimbursement for research and development costs that were actually incurred by a Party for the Development of the Collaboration Product(s) that are the subject of the Third Party Transaction (the Participating Party's share of such amounts (if any) for Development Costs shared by the Parties pursuant to Section 7.1.1 or Section 3.5.7(e) is addressed in Section 7.2.9(a)), or (ii) bona fide pre-payment of research and development costs incurred by the Lead Party after a Party exercised its Opt-Out Right, for the Development of the Collaboration Product(s) that are the subject of the Third Party Transaction. If a Third Party Transaction includes products or intellectual property other than Collaboration Products or intellectual property claiming or Covering Collaboration Products, the Parties shall mutually agree upon a fair and reasonable allocation of the Third Party Transaction Proceeds. Any dispute regarding (x) the fair market value of any equity or debt securities issued in respect of a Third Party Transaction, (y) the fair market value of any other form of consideration paid to, or received by or otherwise recognized by a Party or its Affiliates by or from a Third Party in connection

with a Third Party Transaction or (z) the allocation of Third Party Transaction Proceeds between the Collaboration Products and other products or intellectual property included in the applicable Third Party Transaction, in each case ((x) through (z)), shall be a Financial Dispute.

1.299 "**Third Party Transaction Proceeds Percentage**" means, (a) if a Party exercises its Opt-Out Right prior to the Phase 2 Completion Date, [***] and (b) if a Party exercises its Opt-Out Right on or after the Phase 2 Completion Date, [***]; provided, that if the Third Party Transaction Proceeds result from a Third Party Transaction entered into by the then current Lead Party [***] after a Party exercised its Opt-Out Right, pursuant to which the Third Party assumed all further development funding obligations for the Collaboration Products, then clause (a) shall be deemed to be [***] and clause (b) shall be deemed to be [***]; provided, further, that if the Third Party Transaction Proceeds result from a Third Party Transaction entered into prior to the Opt-Out Date pursuant to which the Third Party assumed all further development funding obligations for the applicable Collaboration Products in the applicable parts of the Territory, then the Third Party Transaction Proceeds Percentage will be [***], even if the Third Party Transaction Proceeds are received by the Lead Party on or after the Opt-Out Date.

1.300 "**Total Development Costs**" has the meaning set forth in **Schedule 7.1.1**.

1.301 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.302 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.303 "**Unlicensed Component**" means (a) any API of a Combination Product that is not an siRNA Directed to the Target or (b) any API that is otherwise administered in a Clinical Trial of a Collaboration Product (in accordance with the protocol for such Clinical Trial) that is not an siRNA Directed to the Target.

1.304 "**Valid Claim**" means a claim of (a) any issued and unexpired Patent Right whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a patent application prosecuted in good faith that has been pending less than [***] years from the date of filing of the earliest patent application to which such patent application claims priority, which claim has not been cancelled, withdrawn or abandoned, or finally rejected by an administrative agency action from which no appeal can be taken.

ARTICLE 2
COLLABORATION MANAGEMENT

2.1 Joint Steering Committee.

2.1.1 Formation. Within fifteen (15) days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"). The JSC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JSC on written notice to the other Party. Each Party shall appoint one of its representatives to serve as a co-chairperson of the JSC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party.

2.1.2 Specific Responsibilities. The JSC shall oversee the Development, Commercialization, Manufacture and other Exploitation of the Collaboration Products in the Territory. In particular, the JSC shall:

(a) review, discuss and coordinate the Parties' activities under this Agreement, including oversight of the JDC, the JCC, the JMC and the JFC, including resolving any disputes that arise in the JDC, the JCC, the JMC or the JFC;

(b) select the Collaboration Products to advance into Clinical Trials;

(c) review, discuss and approve the initial Pre-Clinical Plan and Budget, the initial Phase 1 Development Plan and Budget, the initial Phase 2 Development Plan and Budget and the initial Late Stage Development Plan and Budget, in each case that has been submitted by the JDC;

(d) review and discuss whether a targeting ligand or other delivery technology is a Non-Relevant Organ Delivery Technology;

(e) review, discuss and approve any updates or material amendments to any Development Plan and Budget that have been submitted by the JDC;

(f) determine the Anticipated IND Submission Date;

(g) review, discuss and approve the Manufacturing Plan and any amendments and updates to the Manufacturing Plan that have been submitted by the JMC;

(h) review, discuss and approve the initial Commercialization Plan and Budget and any material amendments thereto that have been submitted by the JCC;

(i) discuss any decision with respect to a Collaboration Product that either Party reasonably anticipates would give rise to a material obligation to a Third Party, including by requiring entry into an In-License with such Third Party;

(j) review, discuss and approve the material terms of any Third Party Transaction and the grant of any other sublicenses by a Party pursuant to Section 6.3 to Develop or Commercialize a Collaboration Product;

(k) review and approve Field Force FTE Rates and any updates thereto;

(l) determine the Anticipated FCS Date for each applicable Collaboration Product and country and the anticipated filing date for the respective Drug Approval Application in each such country;

(m) review, discuss and approve entering into any Product-Specific In-Licenses and discuss potential Core Technology In-Licenses, in each case, pursuant to Section 6.5.1;

(n) discuss whether to accept a Core Technology In-License as an In-License;

(o) [***];

(p) [***];

(q) review, discuss and approve, with respect to Manufacturing Costs for Commercial Supply Requirements that are Manufactured directly by a Party or its Affiliate in such Party's or such Affiliate's facility (and not via a Third Party contract manufacturer), adjustments to standard costs in accordance with **Schedule 1.165**, including with respect to extraordinary occurrences, as jointly proposed by the JMC and JFC; and

(r) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.2 Joint Development Committee.

2.2.1 Formation. Within thirty (30) days after the Effective Date, or as otherwise agreed by the Parties, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**"). The JDC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make

decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JDC on written notice to the other Party. Each Party shall appoint one of its representatives to serve as a co-chairperson of the JDC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party.

2.2.2 Specific Responsibilities. The JDC shall develop the strategies for and oversee the Development of the Collaboration Products in the Territory, and shall serve as a forum for the coordination of Development activities for the Collaboration Products for the Territory. In particular, the JDC shall:

(a) review and discuss the initial Pre-Clinical Plan and Budget, the initial Phase 1 Development Plan and Budget, the initial Phase 2 Development Plan and Budget and the initial Late Stage Development Plan and Budget, submitted to it by the Lead Party, and in each case, submit such Development Plan and Budget for approval by the JSC;

(b) review and discuss any updates or material amendments to any Development Plan and Budget submitted by either Party, and submit such update or material amendment for approval by the JSC;

(c) serve as a forum for discussing the Development activities under each Development Plan and Budget, including any potential Development activities for Collaboration Products for inclusion in a Development Plan and Budget (including new indications);

(d) serve as a forum for discussing strategies for obtaining Regulatory Approvals for the Collaboration Products in the Territory; and

(e) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.3 Joint Commercialization Committee.

2.3.1 Formation. The Parties shall establish a joint commercialization committee (the "**Joint Commercialization Committee**" or "**JCC**") at least [***] months prior to the first Anticipated FCS Date in the Territory. The JCC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JCC; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JCC on written notice to the other Party. Each Party shall appoint one of its representatives to

serve as a co-chairperson of the JCC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party.

2.3.2 Specific Responsibilities. The JCC shall develop the strategies and activities for and oversee the Commercialization of the Collaboration Products in the Territory. In particular, the JCC shall:

(a) review and discuss the initial Commercialization Plan and Budget and submit such Commercialization Plan and Budget for approval by the JSC;

(b) review and discuss any updates or material amendments to the Commercialization Plan and Budget, and submit such update or material amendment for approval by the JSC;

(c) serve as a forum for discussing all Commercialization strategy and the Commercialization activities under the Commercialization Plan and Budget; and

(d) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.4 Joint Finance Committee.

2.4.1 Formation. Within thirty (30) days after the Effective Date, the Parties shall establish a joint finance committee (the "**Joint Finance Committee**" or "**JFC**"). The JFC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JFC; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JFC on written notice to the other Party. Each Party shall appoint one of its representatives to serve as a co-chairperson of the JFC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party.

2.4.2 Specific Responsibilities. The JFC shall:

(a) be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to this Agreement, including such specific responsibilities set forth in ARTICLE 7;

(b) respond to financial related inquiries from the JSC, JDC, the JMC and the JCC, as needed;

(c) discuss, following a request by a Party pursuant to Section 3.1.7(a), Section 3.1.7(b) or Section 4.2.2, the appropriate level of detail to include in a Development Budget, Post-Approval Development Budget or Commercialization Budget, as the case may be, for the applicable activities to be performed during the period covered by such Development Budget, Post-Approval Development Budget or Commercialization Budget;

(d) [***];

(e) review, discuss and propose to the JSC operating principles consistent with Accounting Standards for calculating Manufacturing Costs as set forth in **Schedule 1.165**; and

(f) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.5 Joint Manufacturing Committee.

2.5.1 Formation. Within thirty (30) days after the Effective Date, or as otherwise agreed by the Parties, the Parties shall establish a joint manufacturing committee (the "**Joint Manufacturing Committee**" or "**JMC**"). The JMC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JMC; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JMC on written notice to the other Party. Each Party shall appoint one of its representatives to serve as a co-chairperson of the JMC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party. The JMC shall establish a manufacturing working group to interact on a monthly basis (or more frequent basis as mutually agreed to by the Parties) in order to closely communicate and coordinate Manufacturing activities hereunder.

2.5.2 Specific Responsibilities. The JMC shall:

(a) work with the JSC, JDC and JCC, as appropriate, to be responsible for overseeing Manufacturing activities;

(b) develop the Manufacturing Plan, including to the extent appropriate, for a second source manufacturer for Collaboration Products, for approval by the JSC and amend and update the Manufacturing Plan as necessary for approval by the JSC;

(c) discuss raw material quantities and ordering lead times sufficient to meet the Early Stage Supply Requirements and the Late Stage Development Supply Requirements for Collaboration Products;

(d) review operational issues and quality control data relating to the Manufacture or supply of the Collaboration Products and any related devices;

(e) make recommendations to the JSC regarding capacity planning, supply plans and supply continuity planning for each Collaboration Product for consistency with the forecasts, including consultation with the JDC regarding clinical supply Manufacturing;

(f) review and discuss actual Manufacturing Costs, Clinical Supply Costs, Development Costs (with respect to Manufacturing) and Cost of Goods Sold versus the applicable budget with respect thereto, including key variance drivers, on a quarterly basis;

(g) review, discuss and propose to the JSC whether and to what extent [***];

(h) review, discuss and propose to the JSC whether and to what extent [***];

(i) coordinate and discuss the Manufacture and supply of Collaboration Product hereunder and the manufacture and supply of Collaboration Products (as defined in the applicable Co-Co Collaboration Agreement or License Agreement) under other Co-Co Collaboration Agreements or License Agreements;

(j) [***] the JMC shall review and discuss [***];

(k) review, discuss with the JFC and propose jointly with the JFC to the JSC [***]

(l) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.6 General Provisions Applicable to Joint Committees.

2.6.1 Meetings. Each Joint Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than (a) once each Calendar Quarter during the Term, with respect to the JSC, and (b) once each Calendar Quarter during the Term or as otherwise agreed by the Parties, with respect to all other Joint Committees, in each case ((a) and (b)), commencing from and after the time such Joint Committee is established as provided herein unless the co-chairpersons agree otherwise. All Joint Committee meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons; provided, that each Joint Committee shall meet in person at least twice each Calendar Year, unless otherwise agreed by the Parties. Unless otherwise agreed by the Parties, all in-person meetings of a Joint Committee shall be held on an alternating basis between Regeneron’s facilities and Alnylam’s

facilities. A reasonable number of other representatives of a Party may attend any Joint Committee meeting as non-voting observers (provided, that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in ARTICLE 9). Each Party shall be responsible for all of its own expenses of participating in each Joint Committee. Either Party's representatives on a Joint Committee may call a special meeting of the applicable Joint Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.

2.6.2 Procedural Rules. Each Joint Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Joint Committee shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Each Joint Committee shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative appointed by each Party.

2.6.3 Dispute Resolution.

(a) Joint Committee (other than the JSC) Disputes. In the event there is a dispute at the level of the JDC, JCC, JFC or JMC, the Parties, through such Joint Committee, shall seek to resolve the dispute as promptly as possible, but no later than ten (10) days after a Party has delivered to the other Party a written request to resolve the matter, and in the event that no resolution is reached at the JDC, JCC, JFC or JMC, as applicable, such matter shall be promptly referred to the JSC for resolution.

(b) JSC Disputes. If the JSC, after a period of thirty (30) days from the date a matter is submitted to it for decision (including if the JSC is unable to agree on any Development Plan and Budget or the Commercialization Plan and Budget, or amendment thereto), is unable to make a decision due to a lack of required unanimity, either Party may require that the dispute be submitted to the Executive Officers for resolution by providing written notice to the other Party formally requesting that the dispute be resolved by the Executive Officers and specifying the nature of the dispute. If a dispute is referred to the Executive Officers, then the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within fifteen (15) days after receiving written notification of such dispute or such longer period of time as the Executive Officers may agree in writing. Any final decision mutually agreed to by the Executive Officers with respect to a dispute and set forth in writing shall be conclusive and binding on the Parties. If the Executive Officers cannot resolve such dispute within such fifteen (15) days or such other period as agreed by the Executive Officers, such dispute will be resolved as follows:

(i) for any JSC Dispute other than a [***] provided that any final determination permitted to be made by the Lead Party under this Section 2.6.3(b)(i) shall: [***];

(ii) if the dispute is related to: (A) entering into (or the material terms of) any proposed [***] with respect to rights in or to (including any rights to further Develop or Commercialize) one or more Collaboration Products in the [***]; [***] (each of (A) through (D), a "**Deadlocked Dispute**"), neither Party shall have the right to resolve such Deadlocked Dispute and such Deadlocked Dispute shall remain deadlocked until resolved by mutual agreement of the Parties;

(iii) if the dispute is related to a Financial Dispute or a Legal Dispute, such dispute shall be resolved pursuant to Section 13.5; and

(iv) [***]

(v) if the dispute is related to (A) whether a given activity is an Alnylam Specific Activity (B) whether a targeting ligand or other delivery technology proposed under Section 3.1.12 is a type of Non-Relevant Organ Delivery Technology or [***] (each of clauses (A), (B) and (C), an "**Expert Dispute**"), the Parties will mutually agree on an Expert and will submit such matter for resolution by such Expert in accordance with **Schedule 2**, and the determination of the Expert will be binding on the Parties. For avoidance of doubt, the Parties shall be bound by the determination of such Expert and the JSC shall have no authority to modify or amend the finding of the Expert; or

(vi) [***]

2.6.4 Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a Joint Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Joint Committee shall have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 13.7 or compliance with which may only be waived as provided in Section 13.10. For clarity, the JSC shall serve as a discussion forum only for Core Technology In-Licenses, and the JSC shall not have any decision-making authority with respect thereto (and for clarity, each Party shall have decision-making authority with respect to its respective Core Technology In-Licenses).

2.7 Committees under the Master Agreement and other Co-Co Collaboration Agreements and License Agreements. If agreed to by the Parties, a particular Joint Committee hereunder can be the same as the equivalent committee under the Master Agreement or any other Co-Co Collaboration Agreement or License Agreement (e.g., the JSC hereunder can be the same

committee as the JSC under the Master Agreement or any other Co-Co Collaboration Agreement or License Agreement).

2.8 Sub-Committees and Working Groups. Each Joint Committee may establish sub-committees or working groups to interact on a more frequent basis on specific projects and tasks assigned to them by such Joint Committee; provided, that the authority of such sub-committees or working groups shall not expand beyond the authority of the applicable Joint Committee. Any such sub-committees or working groups shall have no decision-making authority, but shall make recommendations to the applicable Joint Committee for its review and approval.

2.9 Discontinuation of Participation on a Committee. Each Joint Committee shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the Joint Committee; and (b) a Party exercising its Opt-Out Right. Once a Party exercises its Opt-Out Right or if the Parties mutually agree to disband the JSC, all Joint Committees shall be immediately disbanded and shall have no further rights or obligations under this Agreement, and the Lead Party shall, except as otherwise provided in this Agreement, have the right to solely decide, without consultation with the Participating Party, all matters that are subject to the review or approval by such Joint Committee hereunder other than a Financial Dispute, Legal Dispute or Expert Dispute, which shall be resolved pursuant to Section 13.5.

2.10 Alliance Manager. Each Party shall appoint a senior representative who possesses a general understanding of this Agreement and pharmaceutical research, clinical, regulatory, manufacturing and commercialization matters and who shall oversee contact between the Parties for all matters between meetings of each Joint Committee and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "**Alliance Manager**") for so long as neither Party has exercised its Opt-Out Right. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

ARTICLE 3
DEVELOPMENT AND REGULATORY

3.1 Development Activities.

3.1.1 Transition of Development Activities from Master Agreement. To the extent that the Participating Party was performing Development activities with respect to the Target Program under the Master Agreement, the Participating Party shall use Commercially Reasonable Efforts to provide cooperation and assistance to the Lead Party, as reasonably requested by the Lead Party, to enable the Lead Party to assume the continuation of such Development of the Collaboration Products in the Territory pursuant to this Agreement; provided, however, that (a) the Participating Party shall not transition to the Lead Party any Ongoing Candidate Discovery Development Activities that are allocated to the Participating Party (as set forth in the Pre-Clinical Plan and

Budget) and (b) if Regeneron is the Lead Party, Alnylam shall not transition to Regeneron any Alnylam Specific Activities. Such cooperation and assistance shall be provided in a prompt and timely manner.

3.1.2 Pre-Clinical Activities.

(a) Within thirty (30) days after the Effective Date the JSC shall review, revise and approve the proposed initial Pre-Clinical Plan and Budget (which shall be based on the Preliminary Pre-Clinical Plan (as defined in the Master Agreement) provided under the Master Agreement for the Target Program); provided, that the Pre-Clinical Plan and Budget shall not become effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or [***]). Pending such time as the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)) approves the initial Pre-Clinical Plan and Budget (including during the period while the Parties are in the process of entering into this Agreement in accordance with Article 4 of the Master Agreement), the Lead Party may commence Development activities as set forth in, and in accordance with, the Preliminary Pre-Clinical Plan and Budget (as defined in the Master Agreement) for the Target Program, and such activities will be deemed to be performed under the Pre-Clinical Plan and Budget once the initial Pre-Clinical Plan and Budget is so approved.

(b) Each Party shall use Commercially Reasonable Efforts to (i) perform the Development activities assigned to it under the Pre-Clinical Plan and Budget in accordance with the timeline and budget set forth therein and (ii) achieve the goals and objectives set forth in the Pre-Clinical Plan and Budget.

(c) In the event that either Party reasonably believes that [***].

3.1.3 Phase 1 Development Activities.

(a) At least one hundred twenty (120) days prior to the anticipated date of IND submission to the FDA for the first Collaboration Product, as such date is reasonably determined by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)) (the "**Anticipated IND Submission Date**"), the Lead Party, in consultation with the Participating Party, shall provide the JDC with a proposed initial Phase 1 Development Plan and Budget for the JDC's review, discussion and potential modification prior to submission of the initial Phase 1 Development Plan and Budget by the JDC to the JSC for review and approval. Based on its review of the Parties' proposed initial Phase 1 Development Plan and Budget and within thirty (30) days after receipt of such proposal, the JDC shall propose to the JSC an initial Phase 1 Development Plan and Budget. The JSC shall endeavor to approve the Phase 1 Development Plan and Budget within sixty (60) days after receipt of the proposed initial Phase 1 Development Plan and Budget by the JDC, and in no event later than the screening of the first

subject for the first Phase 1 Clinical Trial for a Collaboration Product; provided, that the Phase 1 Development Plan and Budget shall not become effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)).

(b) Each Party shall use Commercially Reasonable Efforts to (i) perform the Development activities assigned to it under the Phase 1 Development Plan and Budget in accordance with the timeline and budget set forth therein and (ii) achieve the goals and objectives set forth in the Phase 1 Development Plan and Budget.

3.1.4 Phase 2 Development Activities.

(a) Within sixty (60) days after the Phase 1 Completion Date, the Lead Party, in consultation with the Participating Party, shall provide the JDC with a proposed initial Phase 2 Development Plan and Budget for the JDC's review, discussion and potential modification prior to submission of the initial Phase 2 Development Plan and Budget by the JDC to the JSC for review and approval. Based on its review of the Parties' proposed initial Phase 2 Development Plan and Budget and within thirty (30) days after receipt of such proposal, the JDC shall propose to the JSC an initial Phase 2 Development Plan and Budget. The JSC shall endeavor to approve the Phase 2 Development Plan and Budget within sixty (60) days after receipt of the proposed initial Phase 2 Development Plan and Budget by the JDC, and in no event later than the screening of the first patient for the first Phase 2 Clinical Trial for a Collaboration Product; provided, that the Phase 2 Development Plan and Budget shall not become effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)).

(b) Each Party shall use Commercially Reasonable Efforts to (i) perform the Development activities assigned to it under the Phase 2 Development Plan and Budget in accordance with the timeline and budget set forth therein and (ii) achieve the goals and objectives set forth in the Phase 2 Development Plan and Budget.

3.1.5 Phase 3 Development Activities.

(a) Within sixty (60) days after the Phase 2 Completion Date, the Lead Party, in consultation with the Participating Party, shall provide the JDC with a proposed initial Late Stage Development Plan and Budget for the JDC's review, discussion and potential modification prior to submission of the initial Late Stage Development Plan and Budget by the JDC to the JSC for review and approval. Based on its review of the Parties' proposed initial Late Stage Development Plan and Budget and within thirty (30) days after receipt of such proposal, the JDC shall propose to the JSC an initial Late Stage Development Plan and Budget. The JSC shall endeavor to approve the Late Stage Development Plan and Budget within sixty (60) days after receipt of the

proposed initial Late Stage Development Plan and Budget by the JDC; provided, that the Late Stage Development Plan and Budget shall not become effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)).

(b) Each Party shall use Commercially Reasonable Efforts to (A) perform the Development activities assigned to it under the Late Stage Development Plan and Budget in accordance with the timeline and budget set forth therein and (B) achieve the goals and objectives set forth in the Late Stage Development Plan and Budget; and the Lead Party shall use Commercially Reasonable Efforts to obtain Regulatory Approval of a Collaboration Product in each of the Major Market Countries.

3.1.6 Operational Discretion. Subject to the terms and conditions of this Agreement, including Sections 3.1.9 and 6.3, the Party to which an activity under any Development Plan and Budget is assigned shall have the right to make operational decisions with respect to how such activity is conducted from an operational perspective; provided that (a) such decisions are consistent with this Agreement and the Development Plan and Budget and (b) such decisions are consistent with customary business practices for other of its similar products.

3.1.7 Development Budgets.

(a) Development Budgets. Until the First Commercial Sale of a Collaboration Product in the first Major Market Country, each Development Plan and Budget will contain (i) a three (3)-Calendar Year rolling budget for the probable Development Costs for the Development activities to be performed during the then-current Calendar Year (broken down by Calendar Quarter) and the next two (2) Calendar Years (broken down by Calendar Year) of such Development Plan and Budget; provided that (A) if six (6) months or more remain in the then-current Calendar Year commencing as of the date of such initial Development Plan and Budget and ending December 31 of such Calendar Year, such partial year shall constitute a full Calendar Year for purposes of this Section 3.1.7(a), and such initial Development Plan and Budget shall include such a budget for such partial year and two (2) Calendar Years thereafter (broken down by Calendar Quarter for the first full Calendar Year and the stub period) and (B) if less than six (6) months remain in the then-current Calendar Year commencing as of the date of such initial Development Plan and Budget and ending December 31 of such Calendar Year, such initial Development Plan and Budget shall include such a budget for such partial Calendar Year and for three (3) Calendar Years thereafter (broken down by Calendar Quarter for the first full Calendar Year and the stub period) (each such budget, a "**Development Budget**") and (ii) the Development Phase Budget with respect to such Development Plan and Budget; provided that, unless otherwise amended pursuant to Section 3.1.8, such Development Phase Budget shall be the Development Phase Budget set forth in the applicable initial Development Plan and Budget. The first full Calendar Year plus any such partial Calendar

Year, if applicable, of the then-current Development Budget shall be binding, and the second and third full Calendar Years of the Development Budget shall be non-binding. The initial Development Budget and initial Development Phase Budget for each Development Plan and Budget, and each update thereto, will be prepared by the Parties based on each Party's good faith estimation, consistent with its standard internal practices, of the probable Development activities to be conducted during the relevant Development Budget period or Development Phase Budget Period, and based on and consistent with the documents and information related to the Collaboration Products prepared by such Party for its internal use and reference in the budgeting process. Upon request by a Party, the JFC shall discuss the appropriate level of detail to include in a Development Budget for the applicable Development activities to be performed during the period covered by such Development Budget.

(b) Post-Approval Development Budgets. Commencing with the First Commercial Sale of a Collaboration Product in a Major Market Country, the Late Stage Development Plan and Budget will contain a three (3)-Calendar Year rolling budget for the probable Development Costs for the Development activities to be performed during the then-current Calendar Year (broken down by Calendar Quarter) and the next two (2) Calendar Years (broken down by Calendar Year); provided that (i) if six (6) months or more remain in the then-current Calendar Year commencing as of the date of such Late Stage Development Plan and Budget and ending December 31 of such Calendar Year, such partial year shall constitute a full Calendar Year for purposes of this Section 3.1.7(b), and such Late Stage Development Plan and Budget shall include such a budget for such partial year and two (2) Calendar Years thereafter and (ii) if less than six (6) months remain in the then-current Calendar Year commencing as of the date of such Late Stage Development Plan and Budget and ending December 31 of such Calendar Year, such Late Stage Development Plan and Budget shall include such a budget for such partial Calendar Year and for three (3) Calendar Years thereafter (each such budget, a "**Post-Approval Development Budget**"). The first full Calendar Year plus any such partial Calendar Year, if applicable, of the then-current Post-Approval Development Budget shall be binding, and the second and third full Calendar Years of the Post-Approval Development Budget shall be non-binding. The initial Post-Approval Development Budget, and each update thereto, will be prepared by the Parties based on each Party's good faith estimation, consistent with its standard internal practices, of the probable Development activities to be conducted during the relevant Post-Approval Development Budget period, and based on and consistent with the documents and information related to the Collaboration Products prepared by such Party for its internal use and reference in the budgeting process. Upon request by a Party, the JFC shall discuss the appropriate level of detail to include in a Post-Approval Development Budget for the applicable Development activities to be performed during the period covered by such Post-Approval Development Budget.

3.1.8 Amendments to Development Plans and Budgets.

(a) The Lead Party, in consultation with the Participating Party, shall (i) review each Development Plan and Budget at least annually during the period covered by such Development Plan and Budget for the purpose of considering appropriate amendments thereto to be proposed to the JDC and (ii) then no later than September 15 of the then-current Calendar Year beginning with the first full Calendar Year of the initial Development Plan and Budget, provide the JDC with a proposed updated Development Plan and Budget for the JDC's review, discussion and potential modification prior to submission of such updated Development Plan and Budget by the JDC to the JSC. Based on its review of the Lead Party's proposed updated Development Plan and Budget and within thirty (30) days after the receipt of such proposal, the JDC shall propose to the JSC an updated Development Plan and Budget. The JSC shall endeavor to approve such updated Development Plan and Budget no later than November 15 of the then-current Calendar Year.

(b) Annual updates to each Development Budget shall contain a proposed Development Budget covering (i) the next Calendar Year, broken down by Calendar Quarter, and (ii) each of the two (2) Calendar Years thereafter, broken down by Calendar Year, in each case ((i) through (ii)), in accordance with the requirements set forth in Section 3.1.7(a). The annual updates to each Development Budget shall further contain any proposed Development activities that were not previously included as Development activities in the then-current Development Plan and Budget (including any new indications).

(c) Annual updates to each Post-Approval Development Budget shall contain a proposed Post-Approval Development Budget covering (i) the next Calendar Year, broken down by Calendar Quarter, and (ii) each of the two (2) Calendar Years thereafter, broken down by Calendar Year, in each case ((i) and (ii)), in accordance with the requirements set forth in Section 3.1.7(b).

(d) In addition to the annual updates, either Party, through its representatives on the JDC, may propose amendments to any Development Plan and Budget at any time until such time as no further Development activities are occurring or expected to occur under such Development Plan and Budget, including amendments to add Development activities to such Development Plan and Budget and amendments to any Development Phase Budget (including new indications).

(e) No annual update or material amendment to a Development Plan and Budget shall be effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]. No amendment to a Development Phase Budget shall be effective unless and until approved by the JSC by consensus or the Executive Officers pursuant to Section 2.6.3(b) or deemed approved by the Participating Party [***] [or approved pursuant to Section 2.6.3(b)(vi)][15].

(f) In the event that Development activities for any Collaboration Products are approved by the JSC by consensus or the Executive Officers pursuant to Section 2.6.3(b) (i.e., without [***] exercising its final decision-making authority) [or pursuant to [***]][16], then the corresponding Baseline Annual Development Plan and Budget (including, for clarity, the Development Plan and Budget for the then-current Calendar Year) and the Development Phase Budget, if applicable shall be adjusted to account for the costs and expenses for such approved Development activities.

[15] Note to Draft: Include this bracketed language only in Co-Co Collaboration Agreements where (1) Alnylam is the initial Lead Party and (2) the Target Program was a CNS Program under the Master Agreement.

[16] Note to Draft: Include this bracketed language only in Co-Co Collaboration Agreements where (1) Alnylam is the initial Lead Party and (2) the Target Program was a CNS Program under the Master Agreement.

3.1.9 Subcontracting. Each Party shall have the right to subcontract any of its Development activities under this Agreement to a Third Party (a "**Third Party Provider**") without the other Party's consent (provided that Alnylam shall not subcontract any activities within the Alnylam Specific Activities or the Ongoing Candidate Discovery Development Activities without Regeneron's prior consent, such consent not to be unreasonably withheld, conditioned or delayed, except that Alnylam may subcontract those activities set forth on **Schedule 3.1.9** to those Third Party Providers as set forth on such schedule to the extent Alnylam subcontracts such activities in the ordinary course of Alnylam's business, which schedule may be updated from time to time by the JSC to include additional Third Party Providers upon Alnylam's reasonable request and Regeneron's consent, not to be unreasonably withheld, conditioned or delayed); provided that any subcontract entered into by a Party pursuant to this Section 3.1.9 must (a) be in writing, (b) be consistent with the terms and conditions of this Agreement, including containing confidentiality provisions at least as protective as those contained in ARTICLE 9, and (c) provide the other Party with the same rights with respect to any intellectual property arising from the subcontracted activities as it would have if the subcontracting Party performed such activities under this Agreement (except that with respect to any subcontract entered into with a Third Party contract manufacturer, such Third Party may retain ownership of any general manufacturing process improvement of general application; provided that such Third Party grants the subcontracting Party a sublicenseable license with respect to any such improvement to the extent related to a Collaboration Product). Without limiting the foregoing, Alnylam shall not subcontract any of its regulatory obligations under this Agreement to a contract research organization unless Alnylam and its Affiliates use such contract research organizations for similar regulatory activities in their normal course of conduct with respect to their other products. In the event the subcontracting Party seeks to subcontract with an academic, governmental, not-for-profit or public institution and is unable to comply with subsection (c) above, then the subcontracting Party may submit a written request to the other Party for its consent to such subcontract through the Alliance Managers. If the other Party fails to respond to such request within [***] weeks after receipt of such written request, such request shall be deemed to have been approved, and the subcontracting Party may proceed with the subcontract. In any event, the subcontracting Party shall (x) oversee the performance by its subcontractors of the activities subcontracted pursuant to this Section 3.1.9 in a manner that would be reasonably expected to result in their timely and successful completion and (y) be responsible and liable for the actions and omissions of its subcontractors. No subcontracting pursuant to this Section 3.1.9 shall relieve the subcontracting Party of any of its obligations, or the other Party of any of its rights, under this Agreement.

3.1.10 [**Proof of Principle Study**. Promptly following mutual agreement on the Proof of Principle Criteria by the Parties, in accordance with and more particularly described in the

Master Agreement, the Lead Party shall identify such Proof of Principle Criteria in writing to the JSC. [***]

3.1.11 Compliance. Each Party shall perform or cause to be performed any and all of its Development activities, including its activities under each applicable Development Plan and Budget, in a good scientific manner and in compliance with all Applicable Law.

3.1.12 Delivery Technology. At any time during the Term, either Party may propose in writing to the other Party that a targeting ligand or other delivery technology is or is not a type of Non-Relevant Organ Delivery Technology, as measured by [***]. Within thirty (30) days of receiving such request, together with reasonable supporting data from the requesting Party, if any, the non-requesting Party may agree or object. Upon any such objection, the proposing Party, if it so elects, may elect to invoke the dispute resolution process set forth in Section 2.6.3(b)(v) to determine if a targeting ligand or other delivery technology is or is not a type of Non-Relevant Organ Delivery Technology. Upon any agreement by the Parties or resolution by the dispute resolution process set forth in Section 2.6.3(b)(v), the JSC will record the applicable classification of the targeting ligand or other delivery technology in its minutes; provided that, for clarity, either Party shall have the right to subsequently dispute the determination made pursuant to this Section 3.1.12 if new information becomes available with respect to such targeting ligand or other delivery technology, and if a new determination is made, the JSC minutes will be updated to reflect such new determination (provided that if (a) there was an initial determination made pursuant to this Section 3.1.12 that a particular targeting ligand or other delivery technology was Non-Relevant Organ Delivery Technology, and (b) it is subsequently determined that such targeting ligand or other delivery technology is not Non-Relevant Organ Delivery Technology, [***].

3.1.13 siRNAs from Other Co-Co Collaboration Agreements or License Agreements. [***]

3.1.14 Additional Collaboration Products. If (a) Regeneron is the Lead Party and (b) prior to the Initiation of a Registration Enabling Trial for the first Collaboration Product hereunder, Regeneron desires to Develop additional Collaboration Products hereunder, [***].

3.1.15 Additional Permitted Dual Sequences. [***]

3.1.16 [**Development of Collaboration Product for use with an Antibody**. In the event that the Lead Party desires to Develop the Collaboration Product for use with an antibody (either as a Combination Product or for co-administration), then, prior to including any such Development activities in a Development Plan and Budget, the Lead Party shall discuss such Development with the Participating Party.][17]

[17] Note to Draft: Include this bracketed provision only when Alnylam is the initial Lead Party in this Agreement.

3.1.17 [***]

3.2 Development Costs.

3.2.1 Development Cost Sharing. Unless and until a Party exercises its Opt-Out Right, subject to Section 3.2.2(a) and Section 3.2.2(b), the Parties shall share Development Costs equally (50%/50%) pursuant to Section 7.1.1.

3.2.2 Development Budget Overruns and Option Thresholds.

(a) Development Budget Overruns. For purposes of determining any budget overages, where Development activities included in a Development Plan and Budget are allocated to both Parties, the applicable Development Budget or the Post-Approval Development Budget will be allocated between the Parties in proportion to activities allocated to each Party in such plan, and if such activities are allocated to only one Party, the applicable Development Budget or Post-Approval Development Budget shall be allocated entirely to such Party. [***]

(b) Option Thresholds. With respect to each Development Plan and Budget, [***].

3.3 Information Exchange. As long as a Party is conducting Development activities under this Agreement, including under a Development Plan and Budget, upon the reasonable request of such Party (the "**Requesting Party**"), the non-Requesting Party shall provide to the Requesting Party Information that is licensed to the other Party under this Agreement to the extent that it is necessary or reasonably useful for the Requesting Party to perform its Development activities under any Development Plan and Budget, or, with respect to the Lead Party as the Requesting Party, for Developing any Collaboration Product or for filing, obtaining or maintaining INDs or Regulatory Approval for any Collaboration Product, including copies of all material scientific information and data related to such Collaboration Product.

3.4 Records and Reports.

3.4.1 Each of Alnylam and Regeneron shall, and shall ensure that its Third Party Providers, maintain complete, current and accurate records of all of its Development activities under this Agreement, including under each Development Plan and Budget, and all data and other information resulting from such Development activities, which records shall (a) be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, (b) properly reflect all work done and results achieved in the performance of such Development activities, and (c) record only such Development activities and

shall not include or be commingled with records of activities that are not conducted under this Agreement. Alnylam or Regeneron, as the case may be, shall retain, or cause to the retained, such records for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law.

3.4.2 Until a Party exercises its Opt-Out Right, each Party shall promptly provide to the JDC a summary of material non-clinical data and Clinical Data with respect to any Development activities under each Development Plan and Budget and, upon the reasonable request by the other Party, shall provide the other Party copies of or access to all non-clinical data and Clinical Data, and other material Information, results, and analyses (including clinical safety data affecting each Collaboration Product or the class (e.g., serious adverse events, emerging safety issues) and other reasonable information to enable Alnylam to conduct platform-wide safety signal analyses) with respect to such Development activities (collectively, "**Development Data**"). If requested by a Party, the Parties shall reasonably agree on timelines to provide such Development Data, and in particular with respect to clinical safety data (but without limiting the foregoing), prior to IND submission to the FDA for the first Collaboration Product, the Parties shall reasonably agree (via the JDC or otherwise) on timelines and procedures for exchange of such safety data and regular meetings of safety personnel, in each case, in order for the Parties to be able to comply with any regulatory reporting requirements.

3.4.3 If a Party exercises its Opt-Out Right, within thirty (30) days following the end of each Calendar Year during which the Lead Party is conducting Development activities, the Lead Party shall provide the Participating Party a summary of material Development activities and shall promptly notify the Participating Party of material developments in the Development and Regulatory Approval of the Collaboration Products in the Major Market Countries.

3.4.4 Notwithstanding anything to the contrary contained herein (including Sections 3.6.1 and 5.1.1), neither Party shall be required to provide to, or otherwise share with, the other Party any data (including Development Data and CMC information) specific to such Party's Proprietary Unlicensed Component, unless otherwise required by a Regulatory Authority.

3.5 Opt-Out Rights.

3.5.1 Each Party shall have the right, subject to Section 3.5.7, to opt-out of its obligation to perform any further Development activities under this Agreement (except, with respect to Alnylam, the continued performance of the Alnylam Specific Activities subject to Section 3.5.7(b)) and its obligation to pay for fifty percent (50%) of the future Development Costs (except, with respect to either Party, the continued obligation to share Development Costs pursuant to Section 3.5.7(e), as applicable) (the "**Opt-Out Right**") by providing written notice of such exercise (an "**Opt-Out Notice**", and the date such Opt-Out Notice is provided, the "**Opt-Out Date**")

to the other Party within thirty (30) days after the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approves the initial Phase 2 Development Plan and Budget.

3.5.2 If a Party has not previously exercised its Opt-Out Right, each Party shall have the right, subject to Section 3.5.7, to exercise its Opt-Out Right by providing an Opt-Out Notice to the other Party within thirty (30) days after the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approves the initial Late Stage Development Plan and Budget.

3.5.3 If a Party has not previously exercised its Opt-Out Right, each Party shall have the right, subject to Section 3.5.7, to exercise its Opt-Out Right by providing an Opt-Out Notice to the other Party at any time after the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approves the initial Phase 2 Development Plan and Budget (but not during the period that is (a) within thirty (30) days after the date that the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approves the initial Phase 2 Development Plan and Budget, which would be handled pursuant to Section 3.5.1, or (b) within thirty (30) days after the date that the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approves the initial Late Stage Development Plan and Budget, which would be handled pursuant to Section 3.5.2).

3.5.4 If a Party has not previously exercised its Opt-Out Right, the Participating Party may exercise its Opt-Out Right pursuant to Section 3.2.2(b); provided, however, that if a Party exercises its Opt-Out Right pursuant to this Section 3.5.4 before the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)) approves the initial Phase 1 Development Plan and Budget, then the Parties shall negotiate in good faith whether to change (and if so, the change to) the royalty rates in Section 7.2.1(a) and the Third Party Transaction Proceeds Percentage based on such Party's contribution to the Development of the Collaboration Products, the status of the Collaboration Products and the commercial prospects for the Collaboration Products.

3.5.5 If a Party has not previously exercised its Opt-Out Right, as a limited exception to the exclusivity obligation in Section 6.7.1, the Acquired Party may exercise its Opt-Out Right in the event an Acquirer has a Competing Program at the time of the closing of the Third Party Acquisition by providing an Opt-Out Notice to the other Party within ten (10) Business Days after the closing of the Third Party Acquisition for the Acquired Party; provided, however, that if the Acquired Party exercises its Opt-Out Right pursuant to this Section 3.5.5 before the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approves the initial Phase 1 Development Plan and Budget, then the Parties shall negotiate in good faith whether to change (and if so, the change to) the royalty rates in Section 7.2.1(a) and the Third Party Transaction Proceeds Percentage based on the Acquired Party's contribution to the Development of the Collaboration Products, the status of the Collaboration Products and the commercial prospects for the Collaboration Products.

3.5.6 [***]

3.5.7 Any Opt-Out Notice shall indicate the subsection of Section 3.5 under which such Party is exercising its Opt-Out Right. If a Party exercises its Opt-Out Right pursuant to Section 3.5.1, Section 3.5.2, Section 3.5.3, Section 3.5.4 or Section 3.5.5 [or Section 3.5.6][18] (such Party, the "**Opt-Out Party**"), then:

(a) if the Opt-Out Party is the Party that is the Lead Party immediately prior to exercising its Opt-Out Right, then the provisions of **Schedule 3.5.7(a)** shall apply;

(b) subject to Section 3.5.7(a), the Opt-Out Party shall no longer have any obligation to perform any Development activities with respect to any Collaboration Product, except that if Alnylam is the Opt-Out Party, Alnylam shall still be required to, at Regeneron's request, perform the Alnylam Specific Activities and use Commercially Reasonable Efforts to perform such Alnylam Specific Activities in accordance with a plan and budget to be reasonably agreed to by the Parties (which budget shall include a mutually agreeable mechanism to address payments by Regeneron to Alnylam for cost overruns that are no more than [***] over the budget); provided that, (i) in the event of a dispute with respect to such plan (including if the Parties are unable to reasonably agree on such plan or amendments thereto), such dispute shall be resolved by Regeneron, provided that Regeneron shall not have the right to include activities in such plan that are not Alnylam Specific Activities and (ii) in the event of a dispute with respect to such budget (including if the Parties are unable to reasonably agree on such budget or amendments thereto), such dispute shall be a Financial Dispute. Regeneron shall pay Alnylam the Alnylam Specific Activities Costs with respect thereto pursuant to Section 7.2.10;

(c) the Lead Party (which may be a New Lead Party, if applicable) shall no longer be required to prepare any Development Plan and Budget, Commercialization Plan and Budget, or any amendments or updates thereto;

(d) the Joint Committees shall automatically terminate and, at the Lead Party's (which may be a New Lead Party, if applicable) request, the Parties shall form a joint working group for the coordination of regulatory, pharmacovigilance and Manufacturing matters, or any other matters as reasonably requested by the Lead Party, after the Opt-Out Date;

[18] Note to Draft: Include this bracketed language only in Co-Co Collaboration Agreements where (1) Alnylam is the initial Lead Party and (2) the Target Program was a CNS Program under the Master Agreement.

(e) except as set forth in Section 3.5.7(e)(i) through Section 3.5.7(e)(iv), or as otherwise provided in this Agreement, the Opt-Out Party shall no longer be responsible for any of the Development Costs, Shared Commercial Expenses or Other Shared Expenses that are incurred after the Opt-Out Date and the Lead Party (which may be a New Lead Party, if applicable) shall be responsible for all costs and expenses incurred in connection with the Development and Commercialization or of the Collaboration Products thereafter;

(i) if the Opt-Out Party exercises its Opt-Out Right pursuant to Section 3.5.1 or Section 3.5.5 after the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approval of the initial Phase 1 Development Plan and Budget but prior to the completion of the Development activities under the Phase 1 Development Plan and Budget (regardless of whether the Phase 1 Completion Date has occurred), then [***];

(ii) if the Opt-Out Party exercises its Opt-Out Right pursuant to Section 3.5.2 or Section 3.5.5 after the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approval of the initial Phase 2 Development Plan and Budget but prior to the completion of the Development activities under the Phase 2 Development Plan and Budget (regardless of whether the Phase 2 Completion Date has occurred), [***];

(iii) if the Opt-Out Party exercises its Opt-Out Right pursuant to (1) Section 3.5.5 after the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]) approval of the initial Late Stage Development Plan and Budget or (2) Section 3.5.3, then (A) if the Opt-Out Party exercises its Opt-Out Right prior to the First Commercial Sale of the first Collaboration Product in the first Major Market Country, [***], and (B) if the Opt-Out Party exercises its Opt-Out Right after the First Commercial Sale of the first Collaboration Product in the first Major Market Country, then the Parties shall continue to share the Development Costs for activities set forth in the Post-Approval Development Budget as of the Opt-Out Date, [***] until the [***] anniversary of the Opt-Out Date;

(iv) if the Opt-Out Party exercises its Opt-Out Right pursuant to Sections 3.5.4 [or 3.5.6][19], then the Parties shall continue to share [***] the Development Costs until the [***] day following the exercise of such Opt-Out Right up to the Development Phase Budget for the applicable Development Plan and Budget;

(f) the Parties shall not share Profits [***] pursuant to Section 7.1 and the provisions of Section 7.2 shall apply;

[19] Note to Draft: Include this bracketed language only in Co-Co Collaboration Agreements where (1) Alnylam is the initial Lead Party and (2) the Target Program was a CNS Program under the Master Agreement.

(g) if the Lead Party is the Opt-Out Party, the licenses granted by the Participating Party to the old Lead Party under Section 6.1.1 through Section 6.1.4 shall terminate and the old Lead Party shall grant the Participating Party (which shall be the New Lead Party) the licenses set forth in Section 6.2.2;

(h) if the Opt-Out Party exercises its Opt-Out Right pursuant to Section 3.5.4, the Opt-Out Party shall have the right pursuant to Section 7.2.6 to recoup the Development Costs it incurred pursuant to Section 7.1.1 with respect to the Development Phase Budget Period during which it exercised its Opt-Out Right other than any Development Costs for which the Opt-Out Party was either reimbursed or which were otherwise covered by Third Party Transaction Proceeds ("**Opt-Out Development Costs**");

(i) if, prior to exercising its Opt-Out Right, the Opt-Out Party received any Third Party Transaction Proceeds as pre-payment of Development Costs, but as of the Opt-Out Date, the Opt-Out Party has not actually incurred Development Costs equal to the amount of such pre-paid Third Party Transaction Proceeds, then the Opt-Out Party shall pay the Lead Party (which may be the New Lead Party), as of the later of the Opt-Out Date and the date the Opt-Out Party is no longer responsible pursuant to Section 3.5.7(e) for any applicable Development Costs, any amount of such pre-paid Third Party Transaction Proceeds that remains after application of such pre-paid Third Party Transaction Proceeds to Development Costs incurred by the Opt-Out Party prior to such date; and

3.6 Regulatory Matters.

3.6.1 Regulatory Responsibilities.

(a) As between the Parties, the Lead Party shall, subject to Section 3.6.1(c), have the sole right to prepare, obtain, and maintain INDs, Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions, and to conduct communications with the Regulatory Authorities, for Collaboration Products in the Territory (which shall include filings or communications with the Regulatory Authorities with respect to Development activities) during such time as it is the Lead Party. The Participating Party shall support the Lead Party, as reasonably requested by the Lead Party, in obtaining INDs and Regulatory Approvals for the Collaboration Products, and in the activities in support thereof, including providing documents or other materials necessary or reasonably useful to obtain any such INDs and Regulatory Approvals and consulting with respect thereto. [***]

(b) All Regulatory Documentation (including all Regulatory Approvals and Product Labeling) relating to the Collaboration Products shall be owned by, and shall be the sole property and held in the name of, the Lead Party or its designated Affiliate, Sublicensee or designee.

(c) [***]

(i) [***]

(ii) The Lead Party shall provide the Participating Party with prior written notice, to the extent the Lead Party has advance knowledge, of any scheduled meeting (including any advisory committee meeting) with a Regulatory Authority in a Major Market Country relating to a Collaboration Product, within [***] Business Days after the Lead Party first receives notice of the scheduling of such meeting (or within such shorter period as may be necessary in order to give the Participating Party a reasonable opportunity to attend such meeting). [***]

(d) [***]

3.6.2 Recall, Market Suspension or Market Withdrawal. The Lead Party shall make every reasonable effort to notify the Participating Party promptly (but in no event later than forty-eight (48) hours) following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Collaboration Product in the Territory, and shall include in such notice the reasoning behind such determination, and any supporting facts. The Lead Party shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Territory; provided, unless and until a Party exercises its Opt-Out Right, that prior to any implementation of such a recall, market suspension, or market withdrawal, the Lead Party shall, to the extent practicable, consult with the Participating Party and shall consider the Participating Party's comments in good faith. If a recall, market suspension, or market withdrawal is mandated by a Regulatory Authority in the Territory, the Lead Party shall initiate such a recall, market suspension, or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 3.6.2, the Lead Party shall be solely responsible for the execution thereof, and the Participating Party shall reasonably cooperate in all such recall efforts. Without limiting ARTICLE 11, (a) if and to the extent that a recall, market suspension, or market withdrawal resulted from a Party's or any of its Affiliate's material breach of its obligations hereunder, or from such Party's or any of its Affiliate's gross negligence or willful misconduct, such Party shall be responsible for the costs and expenses of such recall, market suspension, or market withdrawal incurred by or on behalf of either Party, (b) unless a Party has exercised its Opt-Out Right, except as set forth in the foregoing clause (a), the costs and expenses incurred by or on behalf of either Party as a result of a recall, market suspension, or market withdrawal

of a Collaboration Product shall be included in Other Shared Expenses, and (c) if a Party has exercised its Opt-Out Right, except as set forth in the foregoing clause (a), the Lead Party shall be responsible for the costs and expenses of such recall, market suspension, or market withdrawal incurred by or on behalf of either Party.

3.7 Material Transfer. In the event a Party transfers to the other Party any Materials under this Agreement, the receiving Party shall: (a) use such Materials solely for the purpose of exercising its rights or fulfilling its obligations under this Agreement and for no other purpose; and (b) not transfer such Materials to any Third Party without the providing Party's prior written consent, provided that the receiving Party shall have the right to transfer such Materials to its Sublicensees or subcontractors solely to the extent for such Third Party to conduct the activities on behalf of, or as a Sublicensee of, such receiving Party in furtherance of this Agreement. In the event the Parties anticipate the transfer of any patient samples or patient information, the Parties shall negotiate in good faith and enter into an agreement governing such transfer and subsequent use, in compliance with all Applicable Law.

3.8 [***]

ARTICLE 4
COMMERCIALIZATION

4.1 In General. The Lead Party (itself or through its Affiliates or Sublicensees) shall have the sole right to Commercialize Collaboration Products in the Territory.

4.2 Commercialization Plan and Budget.

4.2.1 General. The Commercialization of the Collaboration Products in the Territory shall be conducted pursuant to the Commercialization Plan and Budget, which shall at a minimum include a reasonably detailed plan for the Detailing and Commercialization of the Collaboration Product in the United States and each other Major Market Country, on a country-by-country basis, and shall further provide that during the first three (3) Calendar Years following the First Commercial Sale of a Collaboration Product in the United States, such Collaboration Product will be Detailed in the primary or secondary position in the United States. The Parties acknowledge and agree that the FTE time necessary to perform a secondary or tertiary Detail is expected to be less than the FTE time necessary to perform a primary position Detail, which would result in the Field Force Costs for secondary and tertiary Details being less than the Field Force Costs for primary Details. At least twenty-four (24) months prior to the Anticipated FCS Date for the first Collaboration Product in the first country in the Territory, the Lead Party shall provide the JCC with a proposed initial Commercialization Plan and Budget for the JCC's review, discussion and potential modification prior to submission of the initial Commercialization Plan and Budget by the JCC to the JSC for review and approval. Based on its review of the Lead Party's proposed initial

Commercialization Plan and Budget and within thirty (30) days after receipt of such proposal, the JCC shall propose to the JSC an initial Commercialization Plan and Budget. The JSC shall endeavor to approve the initial Commercialization Plan and Budget at least eighteen (18) months prior to such Anticipated FCS Date. The initial Commercialization Plan and Budget shall not be effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) or the Lead Party pursuant to Section 2.6.3(b)(i)).

4.2.2 Commercialization Budgets. The Commercialization Plan and Budget will contain a three (3)-Calendar Year rolling budget for the probable Shared Commercial Expenses for the Commercialization activities to be performed during the then-current Calendar Year (broken down by Calendar Quarter) and the next two (2) Calendar Years (broken down by Calendar Year) of the Commercialization Plan and Budget, updated on a rolling three (3)-Calendar Year period basis; provided that (a) if six (6) months or more remain in the then-current Calendar Year commencing as of the date of such initial Commercialization Plan and Budget and ending December 31 of such Calendar Year, such partial year shall constitute a full Calendar Year for purposes of this Section 4.2.2, and such initial Commercialization Plan and Budget shall include such a budget for such partial year and two (2) Calendar Years thereafter (broken down by Calendar Quarter for the first full Calendar Year and the stub period) and (b) if less than six (6) months remain in the then-current Calendar Year commencing as of the date of such initial Commercialization Plan and Budget and ending December 31 of such Calendar Year, such initial Commercialization Plan and Budget shall include such a budget for such partial Calendar Year and for three (3) Calendar Years thereafter (broken down by Calendar Quarter for the first full Calendar Year and the stub period) (each such budget, a "**Commercialization Budget**"). The first full Calendar Year plus any such partial Calendar Year, if applicable, of the then-current Commercialization Budget shall be binding, and the second and third full Calendar Years of the Commercialization Budget shall be non-binding. The initial Commercialization Budget for the Commercialization Plan and Budget, and each update thereto, will be prepared by the Parties based on each Party's good faith estimation, consistent with its standard internal practices, of the probable Commercialization activities to be conducted during the relevant Commercialization Budget period, and based on and consistent with the documents and information related to the Collaboration Products prepared by such Party for its internal use and reference in the budgeting process. Upon request by a Party, the JFC shall discuss the appropriate level of detail to include in a Commercialization Budget for the applicable Commercialization activities to be performed during the period covered by such Commercialization Budget.

4.2.3 Amendments to Commercialization Plans and Budgets. The Lead Party, in consultation with the Participating Party, shall (a) review the Commercialization Plan and Budget at least annually for the purpose of considering appropriate amendments thereto to be proposed to the JCC and (b) then no later than September 15 of the then-current Calendar Year beginning with the first full Calendar Year of the initial Commercialization Plan and Budget, provide the JCC with a proposed updated Commercialization Plan and Budget for the JCC's review, discussion and

potential modification prior to submission of such updated Commercialization Plan and Budget by the JCC to the JSC. Based on its review of the Lead Party's proposed updated Commercialization Plan and Budget and within thirty (30) days after receipt of such proposal, the JCC shall propose to the JSC an updated Commercialization Plan and Budget. The JSC will endeavor to approve such updated Commercialization Plan and Budget no later than November 15 of the then-current Calendar Year. Annual updates to the Commercialization Budget shall contain a proposed Commercialization Budget covering (i) the next Calendar Year, broken down by Calendar Quarter, and (ii) each of the two (2) Calendar Years thereafter, broken down by Calendar Year, in each case ((i) and (ii)), in accordance with the requirements set forth in Section 4.2.2. In addition to the annual update, either Party, through its representatives on the JCC, may propose amendments to the Commercialization Plan and Budget at any time. No update or amendment to the Commercialization Plan and Budget shall be effective unless and until approved by the JSC (or the Executive Officers pursuant to Section 2.6.3(b) [***]).

4.3 Diligence. The Lead Party shall use Commercially Reasonable Efforts to Commercialize a Collaboration Product [***] following receipt of Regulatory Approval therefor in the applicable country in the Territory.

4.4 Compliance with Applicable Law. The Lead Party shall, and shall cause its Affiliates to, comply with all Applicable Law with respect to the Commercialization of Collaboration Products.

4.5 Booking of Sales; Distribution. The Lead Party shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Collaboration Products in the Territory and to perform or cause to be performed all related services. The Lead Party shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Collaboration Products in the Territory.

4.6 Promotional Materials. The Lead Party will be responsible, consistent with the Commercialization Plan and Budget, for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the world.

4.7 Product Trademarks and Domain Names. Subject to Section 4.8, the Lead Party shall have the right, in consultation with the Participating Party unless the Participating Party has exercised its Opt-Out Right, to determine and shall own the Product Trademarks and Domain Names to be used with respect to the Exploitation of the Collaboration Products on a worldwide basis. Neither Party shall, nor it permit its Affiliates to, (a) use in their respective businesses (except, with respect to the Lead Party, under this Agreement), any Trademark that is confusingly similar to,

misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks and Domain Names, or (b) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks and Domain Names.

4.8 Use of Corporate Names.

4.8.1 Unless and until a Party exercises its Opt-Out Right, the Lead Party shall use Commercially Reasonable Efforts to include the Participating Party's Corporate Name with equal prominence on materials related to the Collaboration Products (including Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Collaboration Products), unless to do so would be prohibited under Applicable Law; provided, in the case of multi-product materials that refer to a Collaboration Product as well as other (bio)pharmaceutical products, the prominence of the Participating Party's Corporate Name shall be commensurate with the relative prominence of such Collaboration Product in such materials.

4.8.2 If a Party exercises its Opt-Out Right, the Lead Party shall have no obligation to include the Participating Party's Corporate Names on materials related to the Collaboration Products (including Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Collaboration Products), except that to the extent the Lead Party is required under Applicable Law to include the Participating Party's Corporate Names on materials related to the Collaboration Product (including Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Collaboration Products) it shall do so.

4.8.3 During the Term, the Lead Party shall submit samples of each such Product Labeling, trade packaging, internet pages, social media, samples and Promotional Materials containing the Participating Party's Corporate Name to the Participating Party for its prior approval (which approval shall not be unreasonably withheld, conditioned or delayed) at least fifteen (15) days before the first dissemination of such materials. Failure of the Participating Party to object within such fifteen (15)-day period shall constitute approval of the Lead Party's Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials.

4.9 Commercialization Reports.

4.9.1 Unless and until a Party exercises its Opt-Out Right, commencing upon approval of the initial Commercialization Plan and Budget, promptly after the end of each Calendar Quarter, each Party shall provide to the JCC a summary of material Commercialization activities undertaken by or on behalf of such Party with respect to each Collaboration Product in the Field during such Calendar Quarter, and upon the reasonable request of the other Party, shall provide the other Party with copies of or access to any other material Information and analyses with respect to such Commercialization activities.

4.9.2 If a Party has exercised its Opt-Out Right, approximately twenty-four (24) months prior to, and again approximately twelve (12) months prior to, the expected date of First Commercial Sale of a Collaboration Product, the Lead Party shall provide the Participating Party a written report (in electronic form) summarizing the Commercialization activities (if any) undertaken by or on behalf of the Lead Party with respect to each Collaboration Product in the Field during such Calendar Year. Commencing with the First Commercial Sale of a Collaboration Product in the Territory, such reports shall be provided two (2) times per Calendar Year (for the first two Calendar Quarters and for the last two Calendar Quarters of each Calendar Year). The foregoing reports referred to in this Section 4.9.2 shall be in a level of detail that will provide the Participating Party with an update on the progress of the Commercialization activities. In addition, interim versions of such reports may be requested by the Participating Party with respect to the first Calendar Quarter and third Calendar Quarter of each Calendar Year, it being understood that such interim reports may be less detailed than the regular reports covering two (2) Calendar Quarters.

4.9.3 The Lead Party shall maintain records relating to its sales force, account management, medical science liaison and medical affairs functions FTEs for the Collaboration Products in each country in a manner sufficient to permit the determination of Field Force Cost.

4.10 Commercialization Costs.

4.10.1 Shared Commercial Expenses. Unless a Party exercises its Opt-Out Right, subject to Section 4.10.2, the Parties shall share Shared Commercial Expenses evenly (50%/50%) pursuant to Section 7.1.1.

4.10.2 Commercialization Budget Overruns. Where Commercialization activities included in a Commercialization Plan and Budget are allocated [***].

4.10.3 After Opt-Out. Except as otherwise provided in this Agreement, if either Party exercises its Opt-Out Right, then the Opt-Out Party shall no longer be responsible for any of the Shared Commercial Expenses or Other Shared Expenses that are incurred after the Opt-Out Date, and the Lead Party (which may be a New Lead Party, if applicable), shall be responsible for all costs and expenses incurred in connection with the Commercialization of the Collaboration Products.

ARTICLE 5
MANUFACTURING AND SUPPLY

5.1 Manufacturing Coordination.

[***]

5.2 Early Stage Supply Requirements.

5.2.1 If Regeneron is the Lead Party, Alnylam shall use Commercially Reasonable Efforts to adequately and timely Manufacture and supply the Early Stage Supply Requirements, which Manufacture and supply shall be in accordance with Applicable Law, including GMP, and this Agreement (including the Manufacturing Plan), as well as the Supply Agreement and the Quality Agreement once the Parties have executed the Supply Agreement and the Quality Agreement. If Alnylam is the Lead Party, Alnylam shall use Commercially Reasonable Efforts to adequately and timely Manufacture and supply the Early Stage Supply Requirements, which Manufacture and supply shall be in accordance with Applicable Law, including GMP, and this Agreement (including the Manufacturing Plan).

5.2.2 If Regeneron is the Lead Party, the Parties shall negotiate in good faith and use diligent and good faith efforts to execute and deliver a definitive supply agreement for the supply of the Early Stage Supply Requirements (the "**Supply Agreement**") and related quality agreement (the "**Quality Agreement**") [***].

5.2.3 If Alnylam is the Lead Party, then Alnylam shall comply with the terms of **Schedule 5.2.3** with respect to the Manufacture and supply of Early Stage Supply Requirements.

5.2.4 Alnylam shall be responsible for supplying the Early Stage Supply Requirements. [***]

5.2.5 [***]

5.3 Late Stage Supply Requirements.

5.3.1 Determination of Manufacturer for Late Stage Supply Requirements.

(a) Prior to Opt-Out. [***]

(b) Following Opt-Out. Notwithstanding Section 5.3.1(a), [***].

5.3.2 Regeneron as Lead Party with Alnylam as the Manufacturer. [***].

5.3.3 Regeneron as Lead Party with Regeneron as the Manufacturer.

(a) Technology Transfer. [***]

(b) Additional Technology Transfers. Without limiting the foregoing, [***].

(c) Contracts with Third Party Contract Manufacturers. [***]

(d) Efforts. [***]

5.3.4 [***] **as the Lead Party**. [***]

5.4 Technology Transfer to Alnylam. [***]

5.5 Costs of Manufacture.

[***]

5.6 Certain Alnylam Third Party Contractor Requirements. [***]

5.7 Development of Delivery Systems for Collaboration Products. [***]

5.8 Fill-Finish Manufacturing Activities for Collaboration Products. [***]

ARTICLE 6
GRANT OF RIGHTS

6.1 [Grants to Regeneron. Subject to the terms and conditions of this Agreement, Alnylam hereby grants Regeneron:[20]]

6.1.1 subject to Section 6.4.3, for so long as Regeneron does not exercise its Opt-Out Right, an exclusive (including with regard to Alnylam and its Affiliates), non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Alnylam Product-Specific Patents and the Alnylam Product-Specific Know-How, to perform activities under a Development Plan and Budget and to Exploit the Collaboration Products in the Field in the Territory, which license shall be (a) if neither Party exercises its Opt-Out Right, payment-bearing pursuant to Section 7.1 during the Term and (b) if Alnylam exercises its Opt-Out Right, royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

[20] Note to Draft: If Alnylam is the initial Lead Party, then this Section 6.1 should be replaced with the Alternative Section 6.1 set forth at the end of this Section 6.1.

6.1.2 for so long as Regeneron does not exercise its Opt-Out Right, a non-exclusive, non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Alnylam Core Technology Patents and the Alnylam Core Technology Know-How, to perform activities under a Development Plan and Budget and to Exploit the Collaboration Products in the Field in the Territory, which license shall be (a) if neither Party exercises its Opt-Out Right, payment-bearing pursuant to Section 7.1 during the Term and (b) if Alnylam exercises its Opt-Out Right, royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

6.1.3 subject to Section 6.4.3, for so long as Regeneron does not exercise its Opt-Out Right, an exclusive (including with regard to Alnylam and its Affiliates), non-transferable (except as permitted by Section 13.2), fully paid-up, worldwide license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 6.3, under the Regulatory Approvals and any other Regulatory Documentation that Alnylam or its Affiliates may Control that are related to a Collaboration Product as necessary for purposes of performing any activities under a Development Plan and Budget and for Exploiting such Collaboration Product in the Field in the Territory;

6.1.4 for so long as Regeneron does not exercise its Opt-Out Right, a non-exclusive license, with the right to grant sublicenses in accordance with Section 6.3, to use Alnylam's Corporate Names solely as required to comply with, and in accordance with, Section 4.8, and for no other purpose; and

6.1.5 a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, [***] to Exploit any product in the Territory that does not contain any siRNA, MicroRNA, MicroRNA antagonist or MicroRNA Mimic, or any single or double-stranded oligonucleotide designed to specifically hybridize to RNA and modulate the expression of the intended target.

Notwithstanding the foregoing in this Section 6.1, Regeneron does not receive any rights under the license grants in this Section 6.1 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Alnylam (or any of its Affiliates).

6.1 [ALTERNATIVE SECTION 6.1] [Grants to Alnylam. Subject to the terms and conditions of this Agreement, Regeneron hereby grants Alnylam:[21]]

6.1.1 subject to Section 6.4.3, for so long as Alnylam does not exercise its Opt-Out Right, an exclusive (including with regard to Regeneron and its Affiliates), non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Regeneron Product-Specific Patents and the Regeneron Product-Specific Know-How, to perform activities under a Development Plan and Budget and to Exploit the Collaboration Products in the Field in the Territory, which license shall be (a) if neither Party exercises its Opt-Out Right, payment-bearing pursuant to Section 7.1 during the Term and (b) if Regeneron exercises its Opt-Out Right, royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

6.1.2 for so long as Alnylam does not exercise its Opt-Out Right, a non-exclusive, non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Regeneron Core Technology Patents and the Regeneron Core Technology Know-How, to perform activities under a Development Plan and Budget and to Exploit the Collaboration Products in the Field in the Territory, which license shall be (a) if neither Party exercises its Opt-Out Right, payment-bearing pursuant to Section 7.1 during the Term and (b) if Regeneron exercises its Opt-Out Right, royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

6.1.3 subject to Section 6.4.3, for so long as Alnylam does not exercise its Opt-Out Right, an exclusive (including with regard to Regeneron and its Affiliates), non-transferable (except as permitted by Section 13.2), fully paid-up, worldwide license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 6.3, under the Regulatory Approvals and any other Regulatory Documentation that Regeneron or its Affiliates may Control that are related to a Collaboration Product as necessary for purposes of performing any activities under a Development Plan and Budget and for Exploiting such Collaboration Product in the Field in the Territory;

[21] Note to Draft: If Alnylam is the initial Lead Party, then use this Alternative Section 6.1 in lieu of Section 6.1 above.

6.1.4 for so long as Alnylam does not exercise its Opt-Out Right, a non-exclusive license, with the right to grant sublicenses in accordance with Section 6.3, to use Regeneron's Corporate Names solely as required to comply with, and in accordance with, Section 4.8, and for no other purpose; and

6.1.5 a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, under the [***] to Exploit any product in the Territory containing siRNA (other than a Competing Product).

Notwithstanding the foregoing in this Section 6.1, Alnylam does not receive any rights under the license grants in this Section 6.1 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Regeneron (or any of its Affiliates).

6.2 [Grants to Alnylam.][22]

6.2.1 Subject to the terms and conditions of this Agreement, Regeneron hereby grants Alnylam:

(a) a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Regeneron Technology, to Develop the Collaboration Products solely for purposes of performing Alnylam's obligations as set forth in, and subject to, each applicable Development Plan and Budget and to Manufacture and supply the Early Stage Supply Requirements, and if applicable, the Late Stage Supply Requirements; and

(b) a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, under the [***] to Exploit any product in the Territory containing siRNA (other than a Competing Product).

6.2.2 If Regeneron exercises its Opt-Out Right, subject to the terms and conditions of this Agreement, Regeneron shall grant Alnylam:

[22] Note to Draft: If Alnylam is the initial Lead Party, then this Section 6.2 should be replaced with the Alternative Section 6.2 set forth at the end of this Section 6.2.

(a) subject to Section 6.4.2, an exclusive (including with regard to Regeneron and its Affiliates), non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Regeneron Product-Specific Patents and the Regeneron Product-Specific Know-How, to Exploit the Collaboration Products in the Field in the Territory, which license shall be royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

(b) a non-exclusive, non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Regeneron Core Technology Patents and the Regeneron Core Technology Know-How, to Exploit the Collaboration Products in the Field in the Territory, which license shall be royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country; and

(c) a non-exclusive license, with the right to grant sublicenses in accordance with Section 6.3, to use Regeneron's Corporate Names solely as required to comply with, and in accordance with, Section 4.8, and for no other purpose.

Notwithstanding the foregoing in this Section 6.2, Alnylam does not receive any rights under the license grants in this Section 6.2 to or for any Proprietary Unlicensed Component of a Combination Product controlled by Regeneron (or any of its Affiliates).

6.2 [ALTERNATIVE SECTION 6.2] [Grants to Regeneron.][23]

6.2.1 Subject to the terms and conditions of this Agreement, Alnylam hereby grants Regeneron:

[23] Note to Draft: If Alnylam is the initial Lead Party, then use this Alternative Section 6.2 in lieu of Section 6.2 above.

(a) a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Alnylam Technology, to Develop the Collaboration Products solely for purposes of performing Regeneron's obligations as set forth in, and subject to, each applicable Development Plan and Budget; and

(b) a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, under the [***] to Exploit any product in the Territory that does not contain any siRNA, MicroRNA, MicroRNA antagonist or MicroRNA Mimic, or any single or double-stranded oligonucleotide designed to specifically hybridize to RNA and modulate the expression of the intended target.

6.2.2 If Alnylam exercises its Opt-Out Right, subject to the terms and conditions of this Agreement, Alnylam shall grant Regeneron:

(a) subject to Section 6.4.2, an exclusive (including with regard to Alnylam and its Affiliates), non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Alnylam Product-Specific Patents and the Alnylam Product-Specific Know-How, to Exploit the Collaboration Products in the Field in the Territory, which license shall be royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

(b) a non-exclusive, non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Alnylam Core Technology Patents and the Alnylam Core Technology Know-How, to Exploit the Collaboration Products in the Field in the Territory, which license shall be royalty-bearing pursuant to Section 7.2.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country; and

(c) a non-exclusive license, with the right to grant sublicenses in accordance with Section 6.3, to use Alnylam's Corporate Names solely as required to comply with, and in accordance with, Section 4.8, and for no other purpose.

Notwithstanding the foregoing in this Section 6.2, Regeneron does not receive any rights under the license grants in this Section 6.2 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Alnylam (or any of its Affiliates).

6.3 Sublicenses. Either Party shall have the right to grant sublicenses (or further rights of reference), through multiple tiers, under the licenses and rights of reference granted to [Regeneron][24] in Section 6.1.1, Section 6.1.2, Section 6.1.3 or Section 6.1.4 or to [Alnylam][25] in Section 6.2.1(a) or Section 6.2.2, as applicable; provided that any such sublicenses to Develop or Commercialize a Collaboration Product shall be consistent with the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement and (a) if neither Party has exercised its Opt-Out Right, any such sublicense agreements shall first be approved by the Joint Steering Committee pursuant to Section 2.1.2(j); or (b) if a Party has exercised its Opt-Out Right, any such sublicense agreements with respect to the United States by the Lead Party shall first be approved by the Participating Party, such approval not to be unreasonably withheld, conditioned or delayed; provided, however, that in either case ((a) or (b)), if any such sublicense agreement is between either Party and one or more of such Party's Affiliates, then no prior approval is required. If a Party has exercised its Opt-Out Right, the Lead Party will promptly provide the other Party with a copy of any fully executed sublicense agreement with a Third Party covering any Commercialization sublicense outside the United States granted hereunder. Each such sublicense agreement entered into by a Party (whether before or after a Party has exercised its Opt-Out Right) shall contain a requirement that the Sublicensee comply with confidentiality and non-use provisions that are no less stringent than Section 9.1 with respect to the other Party's Confidential Information. Furthermore, the applicable Party shall use commercially reasonable efforts to ensure that, to the extent possible, each such sublicense agreement by it to a Sublicensee provides that any and all data and results, discoveries, inventions and other Information, whether patentable or not, arising out of the sublicense are owned by such Party or one of its Affiliates; provided that if, after using commercially reasonable efforts, the foregoing is not possible, then such Party shall ensure that it sufficiently Controls all such data and results, discoveries, inventions and other Information in order to grant the licenses to the other Party as contemplated under this Agreement. Notwithstanding any sublicense to a Sublicensee, the sublicensing Party shall remain responsible to the other Party for the performance of all of the sublicensing Party's obligations under, and compliance with, all applicable terms and conditions of, this Agreement, including any obligations delegated to its Sublicensees. For the avoidance of doubt, either Party may grant sublicenses, through multiple tiers, under the licenses granted to such Party under Section 6.1.5 or Section 6.2.1(b), as applicable, without the consent of the other Party and the foregoing provisions of this Section 6.3 shall not apply to such sublicenses.

[24] Note to Draft: Change to "Alnylam" if Alnylam is the initial Lead Party.

[25] Note to Draft: Change to "Regeneron" if Alnylam is the initial Lead Party.

6.4 No Implied License; Retention of Rights.

6.4.1 Except as expressly provided herein, nothing in this Agreement grants either Party or vests in either Party any right, title or interest in and to the Information, Patent Rights, Confidential Information, Trademarks or other intellectual property of the other Party (either expressly or by implication or estoppel), other than the license rights expressly granted hereunder and the assignments expressly made hereunder.

6.4.2 Notwithstanding anything to the contrary in this Agreement, and without limiting any rights granted or reserved to Regeneron pursuant to any other term or condition of this Agreement:

(a) Regeneron hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) all right, title and interest in and to the Regeneron Technology to (i) perform its and their obligations under this Agreement, including to perform all activities under each Development Plan and Budget; and (ii) subject to Section 6.7, develop, obtain and maintain regulatory approvals for, and to manufacture, commercialize, and otherwise exploit any compound or product, other than a Collaboration Product, in any field anywhere in the world; and

(b) Regeneron reserves the right to grant the licenses to Third Parties for the purposes described in Section 6.7.3.

6.4.3 Notwithstanding anything to the contrary in this Agreement, and without limiting any rights granted or reserved to Alnylam pursuant to any other term or condition of this Agreement, Alnylam hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) all right, title and interest in and to the Alnylam Technology to (a) perform its and their obligations under this Agreement, including (i) to perform all activities under each Development Plan and Budget, (ii) to Manufacture and supply the Early Stage Supply Requirements and if applicable, the Late Stage Supply Requirements and (b) subject to Section 6.7, develop, obtain and maintain regulatory approvals for, and to manufacture, commercialize, and otherwise exploit any compound or product, other than a Collaboration Product, in any field anywhere in the world.

6.4.4 [***]

6.5 In-License Agreements.

6.5.1 Entry Into In-Licenses.

[***]

6.5.2 Additional Alnylam In-Licenses. In the event that a Patent Right licensed to Alnylam under an Additional Alnylam In-License actually is or will be infringed by Regeneron's Development, Manufacture or Commercialization of a Collaboration Product in the Field and in the Territory in accordance with this Agreement, then such Additional Alnylam In-License will thereafter automatically be deemed to be an Existing Alnylam In-License on a Collaboration Product-by-Collaboration Product basis, and all rights granted to Alnylam thereunder will be deemed to be "Controlled" by Alnylam and sublicensed to Regeneron under the applicable terms of Section [6.1][26], effective as of the later of (a) the date the applicable Patent Right issues and (b) the date that Regeneron's Development, Manufacture or Commercialization of such Collaboration Product in the Field and in the Territory in accordance with this Agreement under the applicable terms of Section [6.1][27] would infringe such Patent Right in the absence of a license thereunder from Alnylam; provided, for clarity, that the performance of activities as permitted under the safe harbor provision provided in 35 U.S.C. § 271(e)(1) (or other applicable safe harbor exemptions in other countries outside the United States) shall not be deemed to trigger the date under the foregoing clause (b).

6.5.3 Management of In-Licenses. Neither Party shall, and each Party shall cause its Affiliates not to, enter into any subsequent agreement or understanding with any Third Party to an In-License to which such Party or any of its Affiliates is a party that modifies, amends or terminates any such In-License, or waives any right or obligation thereunder, in any way that would adversely affect in any material respect the other Party's rights or interests under this Agreement, including by increasing any of the other Party's obligations or otherwise agreeing to any covenants or obligations imposed on the other Party that would adversely impact the other Party's business outside of this Agreement, in each case, without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed. Neither Party shall, and each Party shall cause its Affiliates not to, commit any acts or permit the occurrence of any omissions that would cause a material breach or termination of any such In-License that would adversely affect in any material respect the other Party's rights or interests under this Agreement.

[26] Change reference to Section 6.2 if Alnylam is the initial Lead Party.
[27] Change reference to Section 6.2 if Alnylam is the initial Lead Party.

6.5.4 In-Licenses. Each Party acknowledges and agrees that the sublicenses and other rights granted by the other Party to such first Party in this Agreement are subject to the terms of any In-Licenses to which such other Party or any of its Affiliates is a party. Each Party granted a sublicense pursuant to this Agreement under any of the In-Licenses of the other Party (or any of its Affiliates) (the Party granted a sublicense, the "**Sublicensed Party**," and the Party granting the sublicense, the "**Sublicensor Party**") shall comply with, and perform and take such actions as may be required to allow the Sublicensor Party to comply with, all applicable terms and conditions of the In-Licenses of the Sublicensor Party to the extent (a) applicable to (i) the Sublicensed Party's rights or obligations relating to the Development, Manufacture or Commercialization of Collaboration Products under this Agreement or (ii) the filing, prosecution, maintenance, extension, defense, enforcement or the further sublicensing of the Alnylam Technology (if Alnylam is the Sublicensor Party) or the Regeneron Technology (if Regeneron is the Sublicensor Party) to the extent relevant to the Sublicensed Party's rights or obligations relating to the Development, Manufacture or Commercialization of Collaboration Products under this Agreement, and (b) the Sublicensed Party has been given written notice or provided a copy of such terms and conditions on or before the later of (i) the Effective Date and (ii) the date on which such In-License is first required to have been provided to the Sublicensed Party hereunder, including any such terms and conditions relating to sublicensing, patent matters, confidentiality, reporting, audit rights, indemnification and diligence. Without limiting the foregoing, (x) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of any In-License and (y) each Sublicensed Party shall prepare and deliver to the Sublicensor Party any reports required under the applicable In-Licenses of the Sublicensor Party sufficiently in advance to enable the Sublicensor Party to comply with its obligations under the applicable In-Licenses, to the extent that the Sublicensed Party had been made aware of such provisions sufficiently in advance of the date on which such compliance is required in order for such Sublicensed Party to properly prepare such reports.

6.5.1 Excluded Agreements. Notwithstanding anything herein to the contrary, Regeneron acknowledges that certain Patent Rights and Information under which Alnylam has rights are in-licensed by Alnylam under the Excluded Agreements. It is understood and agreed that no sublicense is granted to Regeneron by Alnylam under the Excluded Agreements pursuant to this Agreement, and that no Patent Rights or Information licensed to Alnylam under the Excluded Agreements will be Controlled by Alnylam under this Agreement. Alnylam shall be solely responsible for, and shall solely bear, all costs arising under or in connection with any Excluded Agreement.

6.6 Confirmatory Patent License. Each Party shall, if requested to do so by the other Party, promptly enter into confirmatory license agreements in the form or substantially the form

reasonably requested by such other Party for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as the requesting Party considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Alnylam and Regeneron shall have the same rights in respect of the respective intellectual property and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

6.7 Exclusivity.

6.7.1 Exclusivity.

(a) Target Exclusivity. Regardless of whether either Party exercises its Opt-Out Right, during the Term, subject to Section 6.7.2 and Section 6.7.3 and the remainder of this Section 6.7.1(a), and in the case of Alnylam, except as and to the extent set forth in the Existing Alnylam Third Party Agreements and in the case of Regeneron except as and to the extent set forth in the Existing Regeneron Third Party Agreements, in each case, as existing as of the Effective Date (as defined in the Master Agreement) of the Master Agreement, each Party shall not, and shall cause its Affiliates not to, (i) directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization, any Competing Product in the Field in any country in the Territory, or (ii) license, authorize or appoint any Third Party to directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization, any Competing Product in the Field in any country in the Territory.

(A) The provisions of Section 6.7.1(a)(i) and (ii) shall not apply to any Competing Product Directed to the Target using or incorporating only Non-Relevant Organ Delivery Technology; provided that such Competing Product using or incorporating such Non-Relevant Organ Delivery Technology is not administered to or used in (or developed or designed for use or administration in) the Relevant Organ through any route of administration [(including when administered intrathecally)][28].

(B) [The provisions of Section 6.7.1(a)(i) and (ii) shall not apply to any Permitted Competing Products.][29]

[28] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

[29] Note to Draft: Include this bracketed provision only if the Target was a CNS Target under the Master Agreement and there is a Permitted Competing Product hereunder.

(b) siRNA Sequence Exclusivity. Without limiting the provisions of Section 6.7.1(a), during the Term, Alnylam shall not, and shall cause its Affiliates not to, (i) directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization any siRNA that includes the same nucleotide sequence (or a different nucleotide sequence that functionally targets the same nucleotide sequence of the messenger RNA) as a Collaboration Product except [***] (ii) license, authorize or appoint any Third Party to directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization any siRNA that includes the same nucleotide sequence (or a different nucleotide sequence that functionally targets the same nucleotide sequence of the messenger RNA) as a Collaboration Product except for [***]; provided that in each case ((i)-(ii)), [***].

(c) Continuation from Master Agreement. In the event that prior to entering into this Agreement there was a "Competing Program" or "Acquisition Product" with respect to the Target pursuant to Section 5.7.2 of the Master Agreement, then such "Competing Program" or "Acquisition Product" shall also be a Competing Program or Acquisition Product, as applicable, for purposes of this Agreement, and the provisions of Sections 6.7.2 and 6.7.3 shall apply; provided, however, that if the applicable Acquirer and its Affiliates (other than Pre-Existing Affiliates) was allowed to continue to develop, manufacture, commercialize and exploit a given Competing Program under the Master Agreement in accordance with Section 5.7.2(d) of the Master Agreement, then such Acquirer and its Affiliates (other than Pre-Existing Affiliates) shall have the right to continue to develop, manufacture, commercialize and exploit such Competing Program hereunder without being in violation of the provisions of Section 6.7.1(a); provided that the Acquirer shall or shall cause the Acquired Party to (i) continue to fulfill its obligations under this Agreement in all respects, (ii) ensure that the conduct of Competing Program activities is completely independent of the activities conducted under or in connection with this Agreement, (iii) ensure that all Competing Program activities (A) do not use, access or incorporate and are not based on any Alnylam Know-How, Regeneron Know-How or other Confidential Information, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1, and (B) are not covered by and do not incorporate or reference the Alnylam Patents or Regeneron Patents (or any Information or inventions disclosed in any of the foregoing), and (iv) establish reasonable internal safeguards designed to prevent any Alnylam Know-How, Regeneron Know-How or other Confidential Information from being disclosed to, or otherwise utilized by, the Acquirer or any of its Affiliates (other than Pre-Existing Affiliates), in connection with the Competing Program, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1.

6.7.2 Change of Control and Acquired Competing Programs and Products.

(a) If, during the Term, (i) there is a Change of Control of a Party (such Party, the "**Acquired Party**") and as of the effective date of such Change of Control, a Third Party described in the definition of "Change of Control" or any of its Affiliates (other than the Acquired Party, or the Acquired Party's Pre-Existing Affiliates) (the "**Acquirer**") is engaged, directly or indirectly, in any activities that, if carried out by the Acquired Party, would be a breach of the exclusivity obligations set forth in Section 6.7.1 (such activities, a "**Competing Program**"), or (ii) as the result of an acquisition of a Third Party or the assets of a Third Party by a Party or one or more of its Affiliates (the "**Acquiring Party**"), the Acquiring Party directly or indirectly acquires rights to a Competing Product in the Field that would be a breach of the exclusivity obligations set forth in Section 6.7.1 (each such Competing Product, an "**Acquisition Product**" and each transaction described in subsection (i) or (ii), a "**Third Party Acquisition**"); then, the Acquired Party or Acquiring Party, as applicable, shall give the other Party (the "**Non-Acquiring Party**") express written notice thereof within ten (10) Business Days after the closing of such Third Party Acquisition and furthermore the Acquired Party or Acquiring Party, as applicable, shall in its sole discretion do one of the following after the closing of such Third Party Acquisition: (w) by the later of six (6) months after (i) such closing, (ii) the expiration of the Divestment Period pursuant to Section 6.7.2(b) and (iii) the date on which the Parties cease negotiations pursuant to Section 6.7.2(c), as applicable, terminate all development, commercialization and manufacture for purposes of development or commercialization, with respect to such Competing Program or Acquisition Product, as applicable (other than Clinical Trials that a Regulatory Authority requires the Acquired Party or Acquiring Party, as applicable, to continue, which may be continued for no more than twelve (12) months after such closing or such longer period as such Regulatory Authority requires), and deliver to the Non-Acquiring Party a notice of such termination, which notice shall include a covenant that no further development, commercialization or manufacture for purposes of development or commercialization, with respect to such Competing Program or Acquisition Product shall be performed by or on behalf of such Acquired Party or Acquiring Party, as applicable, or any of its Affiliates, to the extent the provisions of Section 6.7.1 would have prohibited such activities; provided, that an Acquired Party or Acquiring Party, as applicable, shall not be prohibited from later divesting its rights in such terminated Competing Program or Acquisition Product, as applicable, whether pursuant to the provisions of this Section 6.7.2 or otherwise; (x) divest its rights in the Competing Program or Acquisition Product to a Third Party pursuant to Section 6.7.2(b); (y) offer the Competing Product Option to the Non-Acquiring Party pursuant to Section 6.7.2(c) or (z) if applicable, exercise the right to continue the Competing Program as set forth in Section 6.7.2(d). If the Acquired Party or Acquiring Party fails to comply with one of the foregoing clauses (w), (x), (y) or (z), then, unless the Parties otherwise agree in writing, the Acquired Party or Acquiring Party, as applicable, shall be in breach of Section 6.7.1.

(b) If the Acquired Party or Acquiring Party, as applicable, chooses to divest its rights in the Competing Program or Acquisition Product, as applicable, to a Third Party, the Acquired Party or Acquiring Party, as applicable, shall commit in writing to the Non-Acquiring Party, within forty-five (45) days of the later of (i) the closing of such Third Party Acquisition and (ii) the date on which the Parties cease negotiations pursuant to Section 6.7.2(c), as applicable, to divest such Competing Program or Acquisition Product, as applicable, to a Third Party within one hundred eighty (180) days after the closing of the Third Party Acquisition, and shall do so within such one hundred eighty (180)-day period; provided, that if the Acquired Party or Acquiring Party, as applicable, fails to complete such divestiture within such one hundred eighty (180)-day period, but can demonstrate to the Non-Acquiring Party's reasonable satisfaction that it used commercially reasonable efforts to effect such divestiture within such one hundred eighty (180)-day period, then, unless otherwise required by Applicable Law, such one hundred eighty (180)-day period shall be extended for such additional reasonable period thereafter as is necessary to enable such Competing Program or Acquisition Product, as applicable, to be in fact divested, not to exceed an additional one hundred and eighty (180) days; provided, however, that such period shall be extended for such period as is necessary to obtain any governmental or regulatory approvals required to complete such divestiture, provided that the Acquired Party or Acquiring Party, as applicable, is using good faith efforts to obtain such approvals (such period, the "**Divestment Period**"). If the Acquired Party or Acquiring Party, as applicable, does not complete the divestiture within the Divestment Period, then the Acquired Party or Acquiring Party, as applicable, shall terminate such Competing Program or Acquisition Product, as applicable pursuant to Section 6.7.2(a), or, provided such Competing Program or Acquisition Product has not previously been the subject of a Competing Product Option, offer the Non-Acquiring Party the option to include the Competing Program or Acquisition Product as a Collaboration Product under this Agreement pursuant to Section 6.7.2(c). Any divestiture of rights under this Section 6.7.2(b) shall not permit the Acquired Party or Acquiring Party, as applicable, or its Affiliates to retain any rights in (other than the right to receive payments) or involvement with the Competing Program or Acquisition Product, as applicable, including rights to direct or influence the course of development or commercialization thereof, or to contribute or receive nonpublic know-how or information of any sort with respect thereto (other than reports showing the basis for calculating payments made to the Acquired Party or Acquiring Party, as applicable, and the right to audit the accuracy of such reports); provided, that the Acquired Party or Acquiring Party, as applicable, may continue to supply the applicable Competing Product to the acquirer and provide other transitional services for a reasonable transitional period until the acquirer is able to establish its own source of supply of such Competing Product and provider for such services. If the Acquired Party or Acquiring Party, as applicable, elects to divest the Competing Program or Acquisition Product, the Acquired Party or Acquiring Party, as applicable shall not be precluded under Section 6.7.1 from conducting any activities (either directly, or with or through any Third Party) with respect to such Competing Program or Acquisition Product during the applicable Divestment Period; provided, that any such activities are subject to appropriate firewall

procedures to segregate such activities (and the personnel conducting such activities) from the activities performed by or on behalf of the Acquired Party or Acquiring Party, as applicable, pursuant to this Agreement to ensure that no Confidential Information of the Non-Acquiring Party and no other information generated under this Agreement is used in connection with such Competing Program or Acquisition Product.

(c) If the Acquired Party or Acquiring Party, as applicable, chooses to offer to the Non-Acquiring Party the option to include the Competing Program or Acquisition Product as a Collaboration Product under this Agreement (the "**Competing Product Option**"), the Acquired Party or Acquiring Party, as applicable, shall provide a Competing Product Option Data Package to the Non-Acquiring Party within thirty (30) days after the closing of such Third Party Acquisition. If the Non-Acquiring Party is interested, in its sole discretion, in exercising the Competing Product Option, it shall provide written notice thereof to the Acquired Party or Acquiring Party, as applicable, within thirty (30) days of receipt of the Competing Product Option Data Package and, promptly thereafter, the Parties shall negotiate in good faith the terms pursuant to which such Competing Program or Acquisition Product would be included as a Collaboration Product under this Agreement. If the Parties do not reach agreement within ninety (90) days after beginning such good faith negotiations, then the Acquired Party or Acquiring Party, as applicable, shall either terminate such Competing Program or Acquisition Product or divest its rights in such Competing Program or Acquisition Product pursuant to this Section 6.7.2.

(d) Notwithstanding anything in this Section 6.7.2 to the contrary, if during the Term there is a Third Party Acquisition as described in Section 6.7.2(a)(i) and either Party has previously exercised its Opt-Out Right or the Acquired Party exercises its Opt-Out Right pursuant to Section 3.5.5, then the Acquirer and its Affiliates (other than Pre-Existing Affiliates) shall have the right to continue to develop, manufacture, commercialize and exploit such Competing Program without being in violation of the provisions of Section 6.7.1(a) (or the provisions of Section 6.7.1(b), but with respect to Section 6.7.1(b), this Section 6.7.2(d) shall only apply [***]; provided that the Acquirer shall or shall cause the Acquired Party to (i) continue to fulfill its obligations under this Agreement in all respects, (ii) ensure that the conduct of Competing Program activities is completely independent of the activities conducted under or in connection with this Agreement, (iii) ensure that all Competing Program activities (A) do not use, access or incorporate and are not based on any Alnylam Know-How, Regeneron Know-How or other Confidential Information, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1, and (B) are not covered by and do not incorporate or reference the Alnylam Patents or Regeneron Patents (or any Information or inventions disclosed in any of the foregoing), and (iv) establish reasonable internal safeguards designed to prevent any Alnylam Know-How, Regeneron Know-How or other Confidential Information from being disclosed to, or otherwise utilized by, the Acquirer or any of its Affiliates (other than Pre-Existing Affiliates), in

connection with the Competing Program, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1.

(e) Notwithstanding anything in this Agreement to the contrary, following the closing of a Change of Control of an Acquired Party, the Parties agree that (x) the Non-Acquiring Party shall not obtain rights or access to the Patent Rights or Information controlled by the Acquirer or any of the Affiliates of such Acquirer (other than the Acquired Party and its Affiliates that exist immediately prior to the closing of such Change of Control and any successor thereto (such Affiliates of the Acquired Party, the "**Pre-Existing Affiliates**")) at the time of such closing (and improvements to such Patent Rights or Information) and any other Patent Rights or Information first acquired or in-licensed by such Acquirer (or any of its Affiliates, other than the Acquired Party and its Pre-Existing Affiliates) from a Third Party after the closing of the Change of Control transaction (and improvements thereto) (so that, for clarity, none of the foregoing in this clause (x) will be treated as Controlled by Alnylam or any of its Affiliates, or by Regeneron or any of its Affiliates, as applicable, based on which Party is the Acquired Party), and (y) the Acquirer and its Affiliates (other than the Acquired Party and its Pre-Existing Affiliates) shall not obtain rights or access to the Patent Rights or Information controlled by the Non-Acquiring Party or any of its Affiliates pursuant to this Agreement, other than in connection with the Exploitation of any Collaboration Products as provided under this Agreement; provided that clause (x) of this Section 6.7.2(e) shall not apply to any Patent Rights or Information controlled by the Acquirer or any of its Affiliates to the extent such Patent Right or Information (i) is used by or on behalf of the Acquired Party or any of its Affiliates in performing any of the Acquired Party's obligations under this Agreement; (ii) is incorporated into any Collaboration Product by or on behalf of the Acquired Party or any of its Affiliates; or (iii) was generated after the closing of such Change of Control through any use of, or access to, any Alnylam Know-How (with respect to Alnylam as the Acquired Party) or any Regeneron Know-How (with respect to Regeneron as the Acquired Party) or is otherwise Covered by any Alnylam Patent (with respect to Alnylam as the Acquired Party) or any Regeneron Patent (with respect to Regeneron as the Acquired Party); provided that, (A) with respect to Alnylam as the Acquired Party, if the Acquirer or any of its Affiliates was party to an agreement with Alnylam or any Pre-Existing Affiliate on or prior to the date of such Change of Control pursuant to which the Acquirer or such Affiliates received a license to any Information or Patent Rights controlled by Alnylam or its Pre-Existing Affiliates other than any Alnylam Product-Specific Know-How or Alnylam Product-Specific Patents, then this clause (iii) shall not apply to any Patent Rights or Information controlled or generated by Acquirer or such Affiliates under such agreement prior to such Change of Control that were not Controlled by Alnylam or any Pre-Existing Affiliate or (B) with respect to Regeneron as the Acquired Party, if the Acquirer or any of its Affiliates was party to an agreement with Regeneron or any Pre-Existing Affiliate on or prior to the date of such Change of Control pursuant to which the Acquirer or such Affiliates received a license to any Information or Patent Rights controlled by Regeneron or its Pre-Existing Affiliates other than any Regeneron

Product-Specific Know-How or Regeneron Product-Specific Patents, then this clause (iii) shall not apply to any Patent Rights or Information controlled or generated by Acquirer or such Affiliates under such agreement prior to such Change of Control that were not Controlled by Regeneron or any Pre-Existing Affiliate. Without limiting the foregoing, in all cases, the Non-Acquiring Party's rights in all Patent Rights and Information Controlled by the Acquired Party or any of its Pre-Existing Affiliates, or any of their respective successors, and all improvements thereto, shall remain licensed to such Non-Acquiring Party after the date of the closing of such Change of Control in accordance with and subject to the terms and conditions of this Agreement and shall not be affected in any manner by virtue of such Change of Control.

6.7.3 Regeneron Exceptions. Notwithstanding the exclusivity obligation in Section 6.7.1 or the exclusive license grants contained in [Section 6.2][30]:

(a) Regeneron reserves the right to grant licenses to Third Parties to use intellectual property owned or otherwise controlled by Regeneron or its Affiliates related to research-enabling technologies, discovery-enabling technologies or manufacturing-related technologies, including Regeneron Technology, and rights to Regeneron Mice, but excluding Alnylam Technology, Regeneron Product-Specific Patents and Regeneron Product-Specific Know-How ("**Excluded Collaboration Technology**"), which licenses during the Term, may be for general purposes not specific to Competing Products (i.e., that is not specific to the Manufacture of any particular Competing Product), but which may involve the exploitation of Competing Products in the Field, and such grant and any associated disclosure or provision of such intellectual property or provision of technical assistance using only such intellectual property in connection therewith shall not constitute a breach of this Agreement (including Section 6.7.1); provided that Regeneron and its Affiliates will not otherwise actively assist any Third Party (other than through the grant of such license or provision of such technical assistance) in developing or commercializing any Competing Product in the Field if doing so would not comply with Section 6.7.1, but, for clarity, may receive license fees, milestones and royalties in connection with exploitation by Third Parties of any Competing Products in the Field generated by such Third Parties.

[30] Note to Draft: Change reference to Section 6.1 if Alnylam is the initial Lead Party.

(b) Regeneron reserves the right to grant licenses to Third Parties to use any clinical, genomic, and molecular data maintained by the Regeneron Genetics Center, other than any such data that is Excluded Collaboration Technology, for any purpose, which may involve activities with respect to Competing Products in the Field, and such grant and any associated disclosure or provision of such data or provision of technical assistance without the use of Excluded Collaboration Technology in connection therewith shall not constitute a breach of this Agreement (including Section 6.7.1); provided that, Regeneron and its Affiliates will not otherwise actively assist any Third Party (other than through the grant of such license or provisions of such technical assistance) in developing or commercializing any Competing Product in the Field if doing so would not comply with Section 6.7.1, but, for clarity, may receive license fees, milestones and royalties in connection with exploitation by Third Parties of any Competing Products in the Field generated by such Third Parties.

(c) The Parties acknowledge and agree that nothing in Section 6.7.1 prevents or limits Regeneron's or its Affiliate's rights to (i) settle any enforcement action or proceeding (including any counterclaim in any such action or proceeding), declaratory judgment action or similar action or claim, or any other litigation or proceeding involving an allegation of infringement or other violation of intellectual property or the invalidity or enforceability of any Patent Right owned or otherwise controlled by Regeneron or any of its Affiliates (other than with respect to intellectual property controlled by Regeneron or its Affiliates as a licensee of Alnylam under this Agreement), including by granting licenses or other rights under any such Patent Right to Third Parties in connection therewith or (ii) enter into an agreement to preempt, and thereby avoid the initiation of, any of the actions, proceedings, claims or other litigation set forth in clause (i), including by granting licenses or other rights under any such Patent Right to Third Parties in connection therewith; provided that, in either case ((i) or (ii)), neither Regeneron nor any of its Affiliates may grant a license or other right under any such Patent Right to a Third Party to make, have made, use, offer to sell, sell or import a generic version of a Collaboration Product in the Field, including any Generic Product, except pursuant to ARTICLE 8.

ARTICLE 7
PAYMENTS

7.1 Sharing of Development Costs and Profits. Unless and until a Party exercises its Opt-Out Right:

7.1.1 Sharing.

(a) Subject to Sections 7.1.1(b) and 7.1.1(c), commencing on the Effective Date and continuing during the Term, the Parties shall share Profits and Development Costs equally (50%/50%) for all Collaboration Products as described in **Schedule 7.1.1**.

(b) Notwithstanding the provisions of Section 7.1.1(a), the following shall apply:

(i) in the event that a Collaboration Product is a Combination Product that includes a Proprietary Unlicensed Component, then the Parties will not share in any revenues from the Proprietary Unlicensed Component and such revenues shall be solely for the benefit of the Party who has the applicable Proprietary Unlicensed Component (provided that with respect to Net Sales, the Parties agree that such allocation shall be in accordance with the definition of Net Sales), and the Parties shall in good faith reasonably allocate and share in accordance with the terms of this Agreement the revenues attributable to the Collaboration Product other than the Proprietary Unlicensed Component of such Collaboration Product; and

(ii) in the event that a Proprietary Unlicensed Component is administered in a Clinical Trial of Collaboration Product hereunder, then [***].

(c) Notwithstanding the provisions of Section 7.1.1(a), solely with respect to the Ongoing Candidate Discovery Development Activities, the Party that is responsible for performing such activities (as set forth in the Pre-Clinical Plan and Budget) shall be solely responsible for the costs thereof, and such costs shall not be included as Development Costs hereunder and shall not be shared by the Parties.

7.1.2 Payments.

(a) The Parties shall make Quarterly Development True-Up and Quarterly Profit True-Up payments as set forth in **Schedule 7.1.1**. If the Lead Party is the Party owing Quarterly Development True-Up or Quarterly Profit True-Up payment(s) based on the calculations in the applicable Development Payment Report or Profit Payment Report, it shall, subject to Section 7.1.4 and Section 7.7, make such payment to the Participating Party within ten (10) days after its delivery to the Participating Party of such Development Payment Report pursuant to Section 7.1.3(f) or Profit Payment Report pursuant to Section 7.1.3(g), as applicable and receipt of an invoice therefor from the Participating Party. If the Participating Party is the Party owing the Quarterly Development True-Up or Quarterly Profit True-Up payment(s) based on the calculations in the applicable Development Payment Report pursuant to Section 7.1.3(f) or Profit Payment Report pursuant to Section 7.1.3(g), it shall, subject to Section 7.1.4 and Section 7.7, make such payment to the Lead Party within ten (10) days after its receipt of such Development Payment Report pursuant to Section 7.1.3(f) or Profit Payment Report pursuant to Section 7.1.3(g), as applicable, from the Lead Party and receipt of an invoice therefor from the Lead Party.

(b) If agreed between the Parties, the Parties may also net the collective payment(s) due under the Development Payment Report and Profit Payment Report. In the event that In-License Payments payable under an In-License are payable on a schedule other than the

schedule set forth in this Agreement for Quarterly Development True-Up or Quarterly Profit True-Up payment(s), the Parties shall discuss in good faith an appropriate schedule upon which the Party that is not party to such In-License shall make such payment to the other Party or its designee, and the Parties shall adjust the amounts payable for the next Quarterly Development True-Up or Quarterly Profit True-Up payment(s) accordingly to credit such paying Party for its pre-payment of any such amounts.

7.1.3 Periodic Financial Reports. Each Party shall prepare and deliver to the other Party the applicable periodic reports specified below:

(a) Within [***] days following the end of each month for the first [***] months of every Calendar Quarter (and for clarity, not for the final month of each Calendar Quarter) commencing with the Calendar Quarter in which the First Commercial Sale of any Collaboration Product occurs in any country in the world, the Lead Party shall provide to the Participating Party a written monthly detailed Net Sales report (in electronic form), in each case with monthly and year-to-date sales in local currency and in each country in which such Collaboration Product is sold, such reporting obligation to commence with the month in which the First Commercial Sale of any Collaboration Product occurs in any country;

(b) Within [***] days after the end of each Calendar Quarter during which a Party performs any Development activities under a Development Plan and Budget, each Party shall provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Calendar Quarter in connection with each Development Plan and Budget, together with a statement of Development Costs and Excess Development Costs incurred by such Party during such Calendar Quarter, which statement shall, with respect to the Development Costs (but, for clarity, not the Excess Development Costs), detail those amounts to be included in the Development Payment Report for such Calendar Quarter. Each Party shall also submit an estimate of the Development Costs and Excess Development Costs incurred by such Party to the other Party within [***] days after the end of such Calendar Quarter;

(c) Within [***] days following the end of each Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale of any Collaboration Product occurs in any country in the world, the Lead Party shall provide to the Participating Party a written report (in electronic form) setting forth, on a country-by-country basis for such Calendar Quarter, for each country, (i) the Net Sales of each Collaboration Product in local currency and in Dollars, (ii) Collaboration Product quantities sold and (iii) gross Collaboration Product sales and an accounting of the deductions from gross sales permitted by the definition of Net Sales. The Lead Party shall also submit an estimate of the foregoing to the Participating Party within [***] days after the end of such Calendar Quarter;

(d) Within [***] days following the end of each Calendar Quarter, each Party that has incurred any Other Shared Expenses, Shared Commercial Expenses or Cost of Goods Sold in that Calendar Quarter shall provide to the other Party a written report (in electronic form) setting forth in reasonable detail the Other Shared Expenses, Shared Commercial Expenses or Cost of Goods Sold incurred by or on behalf of such Party in such Calendar Quarter in the aggregate on a worldwide basis and also on a Major Market Country-by-Major Market Country basis, in local currency and in Dollars. Each Party shall also submit an estimate of the foregoing to the other Party within [***] days after the end of such Calendar Quarter;

(e) Within [***] days following the end of each Calendar Quarter in which the Lead Party receives Third Party Transaction Proceeds, the Lead Party shall provide to the Participating Party a written report (in electronic form) in respect of such Calendar Quarter, providing information regarding the amount of Third Party Transaction Proceeds and the identity of the Third Party. The Lead Party shall also submit an estimate of the foregoing to the Participating Party within [***] days after the end of such Calendar Quarter;

(f) Within [***] days following the end of each Calendar Quarter, the Lead Party shall provide the Participating Party a Development Payment Report (in electronic form) in respect of such Calendar Quarter, combining the information reported by each Party pursuant to Section 7.1.3(b) and showing its calculations in accordance with **Schedule 7.1.1** of the amount of any payments to be made by the Parties hereunder for such Calendar Quarter as contemplated by Section 7.1.1 (including, as applicable, showing the sharing of Development Costs) and, if applicable, providing for the netting of such payments; and

(g) Within [***] days following the end of each Calendar Quarter commencing with the earlier of (i) the Calendar Quarter in which the First Commercial Sale of any Collaboration Product occurs in any country in the world and (ii) the Calendar Quarter in which any of the payments described in Section 7.1.3(d) or Section 7.1.3(e) are due, the Lead Party shall provide to the Participating Party a written Profit Payment Report (in electronic form) in respect of such Calendar Quarter, combining the information reported by each Party pursuant to Section 7.1.3(c), Section 7.1.3(d), and Section 7.1.3(e) and showing its calculations in accordance with **Schedule 7.1.1** of the amount of any payments to be made by the Parties hereunder for such Calendar Quarter as contemplated by Section 7.1.1 (including, as applicable, showing the calculation of the Profit Split or sharing of costs) and, if applicable, providing for the netting of such payments.

7.1.4 Recoupment of Excess Development and Commercialization Costs. Subject to Section 7.1.5:

(a) If, with respect to a Calendar Quarter, after the First Commercial Sale of any Collaboration Product in the Territory, the Profits in such Calendar Quarter are a positive number and the Lead Party is the Party owing a Quarterly Profit True-Up payment:

(i) if the Lead Party has any remaining Recoupment Balance, it shall be permitted to reduce such Quarterly Profit True-Up payment by an amount equal to its current Recoupment Balance; provided that if the Lead Party's current Recoupment Balance is greater than the amount of such Quarterly Profit True-Up payment, then such Quarterly Profit True-Up payment shall not be reduced below zero; and

(ii) if the Participating Party has any remaining Recoupment Balance, the Lead Party shall increase such Quarterly Profit True-Up payment by an amount equal to the Participating Party's current Recoupment Balance.

(b) If at any time, the current Recoupment Balance for each Party is the same amount, then at such time the Recoupment Balance for each Party shall be deemed to be zero and neither Party shall have any further recoupment rights under this Section 7.1.4 or Section 7.2.6, if applicable, with respect to any Excess Development Costs or Excess Commercialization Costs incurred by either Party prior to such time, but for clarity, the provisions of this Section 7.1.4 or Section 7.2.6, if applicable, shall continue to apply with respect to any Excess Development Costs or Excess Commercialization Costs incurred by a Party after such time.

7.1.5 Quarterly Limit on Recoupment.

(a) In no event shall the deductions permitted pursuant to Section 7.1.4 reduce the amount of the Quarterly Profit True-Up payment payable pursuant to Section 7.1.2 with respect to a Calendar Quarter to less [***] of the amount that would otherwise be payable pursuant to Section 7.1.2 in the absence of Section 7.1.4 and any unused deductions as a result of this Section 7.1.5(a) or Section 7.1.4 shall be carried forward to future Calendar Quarters.

(b) In no event shall the increases required pursuant to Section 7.1.4 increase the amount of the Quarterly Profit True-Up payment payable pursuant to Section 7.1.2 with respect to a Calendar Quarter to more than [***] of the amount that would otherwise be payable under Section 7.1.2 in the absence of Section 7.1.4 and any unused increases as a result of this Section 7.1.5(b) or Section 7.1.4 shall be carried forward to future Calendar Quarters.

7.1.6 No Double Counting. Notwithstanding anything to the contrary contained herein, no cost or expense shall be included in Development Costs (or any component thereof), Shared Commercialization Costs (or any component thereof) or Other Shared Expenses (or any component thereof), or in the calculation of Net Sales (or any component thereof), if inclusion

therein would result in a duplication or double-counting of the same cost or expense, hereunder or under the Master Agreement or any other Co-Co Collaboration Agreement or License Agreement.

7.2 Opt-Out Payments. Once a Party exercises its Opt-Out Right:

7.2.1 Royalties. From and after the First Commercial Sale of a Collaboration Product in a country, for each Calendar Quarter during the applicable Royalty Term for such Collaboration Product in such country, the Lead Party shall make royalty payments to the Participating Party on aggregate worldwide annual Net Sales of such Collaboration Product, on a Collaboration Product-by-Collaboration Product basis, at the following royalty rates (the "**Royalties**"):

(a) If the Opt-Out Party exercises its Opt-Out Right prior to the Phase 2 Completion Date:

Aggregate Annual Net Sales of a given Collaboration Product in the Territory in a Calendar Year	**Royalty Rate**
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] in a given Calendar Year	[***]

(b) If the Opt-Out Party exercises its Opt-Out Right after the Phase 2 Completion Date:

Aggregate Annual Net Sales of a given Collaboration Product in the Territory in a Calendar Year	**Royalty Rate**
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] in a given Calendar Year	[***]

If the Opt-Out Party exercises its Opt-Out Right after the First Commercial Sale of a Collaboration Product in the first Major Market Country, the Parties shall negotiate in good faith whether to change (and if so, the change to) the royalty rates in this Section 7.2.1(b) based on the Opt-Out Party's contribution to the Development and Regulatory Approval of the Collaboration Products, the status of the Collaboration Products and the commercial prospects for the Collaboration Products.

7.2.2 Royalty Rate Reductions. Notwithstanding the provisions of Section 7.2.1, if during the Royalty Term for a Collaboration Product in a country:

(a) [***]

(b) [***]

[***]

7.2.3 Manufacturing Technology Transfer Costs Reduction. [***]

7.2.4 Opt-Out Transition Costs Reduction. [***]

7.2.5 In-License Payment Adjustments.

(a) Existing Alnylam In-Licenses. [***]

(i) [***]

(ii) [***]

(b) Existing Regeneron In-Licenses. [***]

(i) [***]

(ii) [***]

(c) Product-Related In-Licenses. [***]

(i) [***]

(ii) [***]

7.2.6 Adjustments for Recoupment of Certain Development and Commercialization Costs. [***]

(a) [***]

(b) [***]

(c) [***]

(d) **Schedule 7.2.6** sets forth example applications of Section 7.2.6(a) through Section 7.2.6(c).

7.2.7 Limit on Reductions or Increases.

(a) [***]

(b) [***]

(c) [***]

(d) [***]

7.2.8 Royalty Reports. Within [***] days following the end of each Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale of any Collaboration Product occurs in any country, (a) the Lead Party shall provide to the Participating Party a written report (in electronic form) setting forth, for such Calendar Quarter, (i) the Net Sales of each Collaboration Product, (ii) Collaboration Product quantities sold, (iii) gross Collaboration Product sales and a reasonably detailed accounting of the deductions from gross sales permitted by the definition of Net Sales and (iv) the amount of any In-License Payments paid by the Lead Party or any of its Affiliates and (b) the Participating Party shall provide to the Lead Party a written report (in electronic form) setting forth, for such Calendar Quarter, the amount of any In-License Payments paid by the Participating Party or any of its Affiliates. Within [***] days following the end of each Calendar Quarter, the Lead Party shall deliver the Royalties payment, if any, due to the Participating Party under Section 7.2.1 for the applicable Calendar Quarter. Such reports shall be broken down on a country-by-country basis with respect to the Major Market Countries and the Lead Party shall report the other countries of the Territory in a consolidated manner.

7.2.9 Third Party Transaction Proceeds.

(a) [***]

(b) [***]

(c) [***]

7.2.10 Other Costs. [***]

7.3 Adjustments to FTE Rates. [***]

7.4 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any Development Costs, Profit Split, Royalty or other payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder. Unless otherwise agreed by the JSC, the financial data in the reports will include calculations in local currency and Dollars.

7.5 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in Dollars. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars at the average rate of exchange for the Calendar Quarter to which such payment relates using the arithmetic mean of the daily rate of exchange, as reported in *Thomson Reuters Eikon* (or any successor thereto) or any other source as agreed to by the Parties.

7.6 Taxes. Either Party may withhold from payments due to the other Party amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. In such case, the payor Party will provide the payee Party all relevant documents and correspondence, and will also provide to the payee Party any other cooperation or assistance on a commercially reasonable basis as may be necessary to enable the payee Party to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. The payor Party will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Apart from any withholding permitted under this Section 7.6 and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies. Notwithstanding the foregoing, if, as a result of a Withholding Action by the paying Party (including any assignee or successor), any withholding or deduction of or on account of taxes, duties, levies, imposts, assessments, deductions, fees and other similar charges ("**Withholding**") is required by Applicable Law and the amount of such Withholding exceeds the amount of Withholding that would have been required if the paying Party had not committed the Withholding Action, then the paying Party shall pay an additional amount to the receiving Party such that, after Withholding from the payment and such additional amount, the receiving Party receives the same amount as it would have received from the paying Party absent such Withholding Action by the paying Party. For the avoidance of doubt, if as a result of a Withholding Action by a receiving Party (including any assignee or successor) the amount of Withholding under the law of the applicable jurisdiction exceeds the amount of such Withholding that would been required in the absence of such Withholding Action by the receiving Party, the paying Party shall be required to pay any additional amount only to the extent that the paying Party would be required to pay any additional amount to the receiving Party pursuant to the preceding

sentence if the receiving Party had not committed such Withholding Action. For purposes of this Section 7.6, "**Withholding Action**" by a Party means (i) a permitted assignment or sublicense of this Agreement (in whole or in part) by such Party to an Affiliate or a Third Party outside of the United States; (ii) the exercise by such Party of its rights under this Agreement (in whole or in part) through an Affiliate or Third Party outside of the United States (or the direct exercise of such rights by an Affiliate of such Party outside of the United States); (iii) a redomiciliation of such Party, an assignee or a successor to a jurisdiction outside the United States; and (iv) any action by such Party that causes this Agreement or any payment to become subject to tax in a jurisdiction outside of the United States or subject any payments to Withholding in any jurisdiction that would not have been required absent such Withholding Action.

7.7 Resolution of Payment Disputes. In the event there is a dispute relating to any payment obligations or reports hereunder, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. If the JFC is unable to resolve such payment dispute within such period then the matter shall be referred to the JSC. The Parties agree that if there is a dispute regarding any payment amount, only the disputed amount shall be withheld from the payment, and the undisputed amount shall be paid within the applicable timeframes.

7.8 Late Fee. A late fee [***] as reported on *Thomson Reuters Eikon* (or any successor thereto) (or another source agreed to by the Parties) on the date that the applicable payment was due may be charged by the Party to whom payment is due with respect to any payment amount from the date such payment amount was originally due under the terms of this Agreement until such payment amount is actually paid by one Party to another Party unless such payment amount is disputed pursuant to Section 7.7, in which case the foregoing late fee shall commence on the date such dispute is resolved.

7.9 Books and Records. Each Party shall (a) keep proper books of record and account in which full, true and correct entries (in conformity with Accounting Standards) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement; (b) keep such books of record and account for at least [***] Calendar Years following the Calendar Year to which they pertain (or such longer period to the extent required by Applicable Law) and (c) keep such books of record and account to the extent related to this Agreement in a readily available and organized form to allow an independent auditor to verify the accuracy of all financial, accounting and numerical information provided in an efficient manner. To the extent a Party is not in compliance with clause (c) of this Section 7.9, such Party shall be responsible for any additional fees charged by the independent auditor to the other Party as a result of additional time spent by the independent auditor assembling or organizing such information.

7.10 Audits and Adjustments.

7.10.1 Audit. Each Party shall have the right, upon no less than [***] advance written notice and at such reasonable places, times and intervals and to such reasonable extent as such Party shall request, not more than once during any Calendar Year, to have the books of record and account of the other Party to the extent relating to this Agreement for the preceding [***] Calendar Years audited by an independent and nationally recognized accounting firm of its choosing and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided, that absent evidence of fraud, gross negligence or willful misconduct no period may be subjected to audit more than [***].

7.10.2 Results; Costs; Confidentiality. The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party by notice to the other Party within [***] days after delivery. [***] Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the results of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in ARTICLE 9. At the request of the Party being audited prior to the audit, the auditing Party shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such accounting firm to retain all such information in confidence pursuant to such confidentiality agreement.

7.10.3 Reconciliation. If any examination or audit of the records described above discloses an overbilling or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.10.2, the Party that over-billed or underpaid shall pay the same to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to Section 7.10.1.

7.10.4 Binding and Conclusive. Upon the expiration of the three (3) year period following the end of any Calendar Year, the calculation of the amounts payable with respect to such Calendar Year shall be binding and conclusive upon the Parties.

7.11 Accounting Standards. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with Accounting Standards, as generally and consistently applied.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 Ownership of Intellectual Property.

8.1.1 Ownership of Technology. Subject to Section 3.6.1(b) and Section 8.1.2, as between the Parties: (a) Regeneron shall own and retain all right, title and interest in and to any and all (i) Regeneron Collaboration IP and (ii) other Information, inventions, Patent Rights, and other intellectual property rights that are owned or otherwise Controlled by Regeneron, its Affiliates or its or their Sublicensees, including the Regeneron Technology, and (b) Alnylam shall own and retain all right, title and interest in and to any and all (i) Alnylam Collaboration IP and (ii) other Information, inventions, Patent Rights, and other intellectual property rights that are owned or otherwise Controlled by Alnylam, its Affiliates or its or their Sublicensees, including the Alnylam Technology. Regeneron shall own and retain all right, title and interest in and to any and all Regeneron Background Technology. Alnylam shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to Regeneron, without additional compensation, all right, title and interest in and to any Regeneron Background Technology Improvements as is necessary to fully effect the ownership thereof as provided for in this Section 8.1.1. Alnylam shall own and retain all right, title and interest in and to any and all Alnylam Background Technology. Regeneron shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to Alnylam, without additional compensation, all right, title and interest in and to any Alnylam Background Technology Improvements as is necessary to fully effect the ownership thereof as provided for in this Section 8.1.1.

8.1.2 Ownership of Joint Collaboration IP. Subject to Section 3.6.1(b), as between the Parties, the Parties shall each own an equal, undivided interest in and to any and all Joint Collaboration IP. Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates and Sublicensees to so disclose, the development, making, conception or reduction to practice of any Joint Collaboration IP. Subject to the licenses and rights of reference granted under Section 6.1 and Section 6.2 and the Parties' respective exclusivity obligations under Section 6.7, (a) each Party shall have the right to Exploit the Joint Collaboration IP without a duty of seeking consent or accounting to the other Party and (b) each Party hereby grants to the other Party a non-exclusive license to such Party's interest in the Joint Collaboration IP for all purposes. Each Party shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to the other Party, without additional compensation, all such right, title and interest in and to any Joint Collaboration IP as is necessary to fully effect the joint ownership thereof as provided for in this Section 8.1.2.

8.1.3 United States Law. The determination of whether Information and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent Rights, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States irrespective of where such conception, discovery, development or making occurs. To the extent that the Applicable Law in any jurisdiction other than the United States affects the

ownership of intellectual property, as a matter of law, in a manner that is inconsistent with the application of Applicable Law in the United States, the Parties shall assign, transfer and otherwise convey, to the other Party, without additional compensation, all such right, title and interest in and to any applicable intellectual property as is necessary to fully effect the ownership thereof as provided for in this Section 8.1.3.

8.1.4 Assignment Obligation. Each Party shall cause all Persons who perform Development activities, Non-Approval Trials, Manufacturing activities or regulatory activities for such Party under this Agreement to be under an obligation to assign their rights in any Information and inventions resulting therefrom to such Party, except (a) if Applicable Law requires otherwise, (b) subject to Section 3.1.9, in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment, or (c) in the case of any Third Party services provider (such as a contract manufacturer or contract research organization), with respect to any Information or inventions that constitute improvements to the background intellectual property of such Third Party, in which case ((a) through (c)), such Party shall use commercially reasonable efforts to obtain a suitable license, or right to obtain such a license, with respect to such Information and inventions, it being understood and agreed that in the case of Third Party contract manufacturers and other service providers it may be commercially reasonable not to obtain a license, [***] Third Party contract manufacturers are set forth in ARTICLE 5.

8.1.5 Control of Product-Specific Know-How and Product-Specific Patents.

(a) Alnylam shall ensure that it sufficiently Controls (a) any and all Information first owned or otherwise controlled (through license or otherwise) by Alnylam or any of its Affiliates after the Effective Date that would otherwise be Alnylam Product-Specific Know-How if Controlled by Alnylam and (b) any and all Patent Rights first owned or otherwise controlled (through license or otherwise) by Alnylam or any of its Affiliates after the Effective Date that would otherwise be Alnylam Product-Specific Patents if Controlled by Alnylam, in each case (a) and (b), such that Alnylam can grant all rights and licenses to Regeneron hereunder with respect to such Information and Patent Rights as Alnylam Product-Specific Know-How or Alnylam Product-Specific Patents, respectively. Notwithstanding the foregoing, this Section 8.1.5(a) shall not apply to any Information or Patent Rights owned or controlled by an Acquiror or its Affiliates prior to the closing of a Change of Control of Alnylam, or to any commitments made by an Acquiror or its Affiliates prior to such closing with respect to later-developed or later-acquired Information or Patent Rights.

(b) Regeneron shall ensure that it sufficiently Controls (a) any and all Information first owned or otherwise controlled (through license or otherwise) by Regeneron or any of its Affiliates after the Effective Date that would otherwise be Regeneron Product-Specific Know-How if Controlled by Regeneron and (b) any and all Patent Rights first owned or otherwise

controlled (through license or otherwise) by Regeneron or any of its Affiliates after the Effective Date that would otherwise be Regeneron Product-Specific Patents if Controlled by Regeneron, in each case (a) and (b), such that Regeneron can grant all rights and licenses to Alnylam hereunder with respect to such Information and Patent Rights as Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents, respectively. Notwithstanding the foregoing, this Section 8.1.5(b) shall not apply to any Information or Patent Rights owned or controlled by an Acquiror or its Affiliates prior to the closing of a Change of Control of Regeneron, or to any commitments made by such Acquiror or its Affiliates prior to such closing with respect to later-developed or later-acquired Information or Patent Rights.

8.2 Prosecution and Maintenance of Patents.

8.2.1 Prosecution and Maintenance of Product-Related Patents.

(a) Prosecution and Maintenance.

(i) Subject to Section 8.2.1(b), [***].

(ii) In the event that [***] is the Lead Party:

[***]

(iii) In all cases, in the event that [***] is the Lead Patent Party,

(A) [***] shall prepare, file, prosecute, and maintain the Product-Related Patents in a manner that is in the best interests of the Collaboration Products hereunder (including to reasonably maximize the scope of any Patent Rights that could fall within the Product-Related Patents), and without taking into account any other products other than Collaboration Products [(provided that, [***]

(B) [***]

(C) [***]

(b) Filing Countries. [***]

(c) [***]

8.2.2 Prosecution and Maintenance of Alnylam Core Technology Patents that are not also Joint Collaboration Patents[or Alnylam Delivery Patents][31]**.** [***]

[31] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

8.2.3 [***]

8.2.4 Prosecution and Maintenance of Regeneron Core Technology Patents that are not also Joint Collaboration Patents. [***]

8.2.5 Cooperation. [***]

8.2.6 Patent Term Extension and Supplementary Protection Certificate. [***]

8.2.7 Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this ARTICLE 8, neither Party shall have the right to make an election under 35 U.S.C. § 102(c) when exercising its rights under this ARTICLE 8 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. § 100(h).

8.2.8 Patent Listings.

[***]

8.3 Enforcement of Patents and Information.

8.3.1 Notices. Each Party shall promptly notify the other Party in writing of any (a) known or suspected infringement of any Alnylam Technology or Regeneron Technology or (b) unauthorized use or misappropriation of any Confidential Information or Information of a Party by a Third Party of which such Party becomes aware, in each case, to the extent such alleged infringing, unauthorized or misappropriating activities involve, as to any Collaboration Product, a Competing Product with respect thereto in the Field (the "**Competitive Infringement**").

8.3.2 Product-Related IP.

[***]

8.3.3 Alnylam Core Technology Patents and Alnylam Core Technology Know-How that are not also Joint Collaboration IP[or Alnylam Delivery Patents][32]**.** [***]

[32] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

8.3.4 Regeneron Core Technology Patents and Regeneron Core Technology Know-How that are not also Joint Collaboration IP. [***]

8.3.5 Generic Competition. Notwithstanding the foregoing, if either Party (a) reasonably believes that a Third Party may be filing or preparing or seeking to file a generic or abridged Drug Approval Application that refers or relies on Regulatory Documentation submitted by either Party to any Regulatory Authority, whether or not such filing may infringe the Product-Related Patents[or Alnylam Delivery Patents][33]; (b) receives any notice of certification regarding any Product-Related Patent[or Alnylam Delivery Patent][34] pursuant to the U.S. "Drug Price Competition and Patent Term Restoration Act" of 1984 (21 United States Code §355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)) ("**ANDA Act**") claiming that any such Patent Rights are invalid or unenforceable or claiming that any such Patent Rights will not be infringed by the Manufacture, use, marketing or sale of a product for which an application under the ANDA Act is filed; or (c) receives any equivalent or similar certification or notice in any other jurisdiction, in each case ((a) through (c)), it shall (i) notify the other Party in writing identifying the alleged applicant or potential applicant and furnishing the information upon which determination is based and (ii) provide such other Party with a copy of any such notice of certification within ten (10) days of the date of receipt, and the Parties' rights and obligations with respect to any legal action as a result of such certification shall be as set forth in Section 8.3.2 and Section 8.3.6.

8.3.6 Cooperation and Settlement. The Parties agree to cooperate fully in any Infringement Action pursuant to this Section 8.3. If a Party brings such an Infringement Action, the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any Infringement Action in accordance with this Section 8.3 shall have the right to settle such claim only with the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed; except that if such other Party has exercised its Opt-Out Right, the Party entitled to bring such Infringement Action shall have the right to settle such claim without such other Party's consent; provided, however, that such Party shall not have the right to settle such Infringement Action in a manner that involves an admission of invalidity or unenforceability with respect to Patent Rights Controlled by such other Party (including Joint Collaboration Patents), without the prior consent of the other Party, such consent to be granted or withheld in its sole discretion. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court.

[33] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

[34] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

8.3.7 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of an Infringement Action described in Section 8.3.2, Section 8.3.3, Section 8.3.4 and Section 8.3.5 (whether by way of settlement or otherwise) with respect to a Competitive Infringement shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be:

(a) if neither Party has exercised its Opt-Out Right, shared [***] by the Parties;

(b) if a Party has exercised its Opt-Out Right, and the Lead Patent Party controlled such Infringement Action, retained by such Lead Patent Party; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales or profit with respect to a Collaboration Product, then the Opt-Out Party shall receive either (i) if the Opt-Out Party exercised its Opt-Out Right prior to the Phase 2 Completion Date, [***] of such attributable amount of such award or settlement or (ii) if the Opt-Out Party exercised its Opt-Out Right on or after the Phase 2 Completion Date, [***] of such attributable amount of such award or settlement; or

(c) if a Party has exercised its Opt-Out Right, and the non-Lead Patent Party controlled such Infringement Action, [***] to such non-Lead Patent Party and [***] to the Lead Patent Party.

8.4 Administrative Proceedings.

8.4.1 Each Party shall promptly notify the other Party in writing upon receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, post-grant review, inter partes review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to any of the Product-Related Patents[or Alnylam Delivery Patents][35]. The Parties shall thereafter consult and reasonably cooperate to determine a course of action with respect to any such proceeding and shall reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms; provided, however, that, except as otherwise agreed by the Parties, and except as set forth below in Section 8.4.2, the Party that has the right to prosecute such Product-Related Patent[or Alnylam Delivery Patent, as applicable][36], shall control and have final decision-making authority with respect to any such proceeding relating to such Product-Related Patent[or Alnylam Delivery Patent, as applicable][37].

8.4.2 If any proceeding under Section 8.4.1 involves Patent Rights involved in an Infringement Action under Section 8.3.2, Section 8.3.3, Section 8.3.4 or Section 8.3.5, or an invalidity or unenforceability action under Section 8.5, any decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, shall be made by the Party controlling such Infringement Action or such invalidity or unenforceability action.

8.4.3 All costs and expenses incurred in connection with any proceeding under this Section 8.4 will be borne in the same manner as costs and expenses incurred with respect to prosecution and maintenance of such Patent Rights pursuant to Section 8.2.

8.5 Invalidity or Unenforceability Defenses or Actions.

8.5.1 Notices. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability (except as made in an administrative proceeding under Section 8.4) of any of the Product-Related Patents[or Alnylam Delivery Patents][38] by a Third Party, including in a declaratory judgment action or similar action or claim filed by a Third Party or as a defense or as a counterclaim in any Infringement Action with respect to a Competitive Infringement initiated pursuant to Section 8.3.2, Section 8.3.3, Section 8.3.4 or Section 8.3.5, in each case, of which such Party becomes aware.

[35] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[36] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[37] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[38] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

8.5.2 Product-Related Patents[and Alnylam Delivery Patents][39]. [***]

8.5.3 Alnylam Core Technology Patents that are not also Joint Collaboration Patents[or Alnylam Delivery Patents][40]. Alnylam shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Alnylam Core Technology Patents that are not also Joint Collaboration Patents[or Alnylam Delivery Patents][41] at its own cost and expense.

8.5.4 Regeneron Core Technology Patents that are not also Joint Collaboration Patents. Regeneron shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Regeneron Core Technology Patents that are not also Joint Collaboration Patents at its own cost and expense.

8.5.5 Cooperation. With respect to Product-Related Patents[and Alnylam Delivery Patents][42], each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 8.5, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party shall keep the other Party reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim, or counterclaim; provided, however, that if a Party has exercised its Opt-Out Right, the foregoing consultation obligation will be limited to only those Product-Related Patents[and Alnylam Delivery Patents][43] Controlled by such Party. In connection with the activities set forth in this Section 8.5, the controlling Party shall consider in good faith any comments from the other Party, and each Party shall consult with the other as to the strategy for the defense of the Product-Related Patents[and Alnylam Delivery Patents][44]; provided, however, that if a Party has exercised its Opt-Out Right, the foregoing consultation obligation will be limited to only those Patent Rights Controlled by such Party.

[39] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[40] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[41] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[42] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[43] Note to Draft: Include this bracketed language only if the Target is a CNS Target.
[44] Note to Draft: Include this bracketed language only if the Target is a CNS Target.

8.5.6 Costs and Expenses. Unless a Party has exercised its Opt-Out Right, the Parties shall share [***] the Out-of-Pocket Costs (other than the costs and expenses of the non-controlling Party's participation in any claim, suit or proceeding in the Territory with independent counsel of such Party's choice as provided in Section 8.5.2) incurred in defending a claim, suit or proceeding under Section 8.5.2 with respect to Product-Related Patents as Other Shared Expenses. If a Party has exercised its Opt-Out Right, then (a) the defending Party shall bear all costs and expenses (other than the costs and expenses of the non-controlling Party's participation in any claim, suit or proceeding in the Territory with independent counsel of such Party's choice as provided in Section 8.5.2) incurred in defending a claim, suit or proceeding under Section 8.5.2 with respect to Product-Related Patents after the Opt-Out Date, and (b) if the defending Party is the Lead Party, the Lead Party may offset up to [***] of such costs and expenses in a given Calendar Quarter incurred in defending a claim, suit or proceeding under Section 8.5.2 with respect to Product-Related Patents after the Opt-Out Date against any amounts otherwise owed to the Participating Party under this Agreement for such Calendar Quarter subject to Section 7.2.7(c).

8.6 Infringement Claims by Third Parties.

8.6.1 Notices. If the Development, Manufacture or Commercialization of a Collaboration Product in the Field pursuant to this Agreement results in, or may result in, an infringement action by a Third Party alleging infringement of such Third Party's intellectual property (a "**Third Party Infringement Action**"), the Party first receiving notice thereof shall promptly notify the other Party thereof in writing.

8.6.2 Defense. [***]

8.6.3 Settlement. [***]

8.6.4 Costs and Expenses; Recovery. [***]

8.7 Product Trademarks and Domain Names.

8.7.1 Ownership and Prosecution of Product Trademarks and Domain Names. The Lead Party shall own all right, title, and interest to the Product Trademarks and Domain Names in the Territory, and shall be responsible for the registration, prosecution, maintenance, enforcement and defense thereof. The Parties shall share equally (50%/50%) the Out-of-Pocket Costs (other than the costs and expenses of the Participating Party's participation in any claim, suit or proceeding with respect to the Product Trademarks and Domain Names with independent counsel of such Party's choice) incurred in the with respect to the Product Trademarks and Domain Names as Other Shared Expenses, unless a Party has exercised its Opt-Out Right, in which case the Lead

Party shall bear all such Out-of-Pocket Costs (other than the costs and expenses of the Participating Party's participation in any claim, suit or proceeding with respect to the Product Trademarks and Domain Names with independent counsel of such Party's choice) incurred after the Opt-Out Date. The Participating Party shall provide all assistance and documents reasonably requested by the Lead Party in support of its prosecution, registration, maintenance, enforcement and defense of the Product Trademarks and Domain Names.

8.7.2 Ownership of Corporate Names. As between the Parties, each Party shall retain all right, title and interest in and to its respective Corporate Names.

8.8 Discussion of Potential Material Intellectual Property Issues. Each Party's legal/intellectual property department shall keep the other Party's legal/intellectual property department reasonably apprised of any potential material Patent Right or other intellectual property-related issue with respect to activities under this Agreement, which may be made pursuant to a mutually acceptable and customary common interest agreement entered into by the Parties; provided that the foregoing shall not impose any duty on either Party to conduct or obtain freedom-to-operate or validity or similar opinions of counsel or Patent Right or other intellectual property clearance searches to the extent not already conducted or obtained by such Party.

8.9 Intellectual Property that Relates to Multiple Programs. [***]

8.10 [**Transition of Patent Matters**. Upon Regeneron's request, subject to Section 8.2.1(c), Alnylam shall use commercially reasonable efforts to promptly provide Regeneron with the appropriate documents for the transfer of responsibility and control of preparation, filing, prosecution, and maintenance of the Product-Related Patents in the Territory and reasonably cooperate with Regeneron with respect to such transfer, including executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to (a) enable Regeneron to apply for and to prosecute, maintain, defend and enforce the Product-Related Patents in the Territory, and (b) obtain and maintain any Patent Right extensions, supplementary protection certificates, and the like with respect to the Product-Related Patents, in each case ((a) and (b)), to the extent provided for in this Agreement. Alnylam shall promptly inform Regeneron of any matters coming to Alnylam's attention that may materially affect the preparation, filing, prosecution, or maintenance of any such Product-Related Patents.][45]

[45] Note to Draft: Include this bracketed provision only if Regeneron is the initial Lead Party.

ARTICLE 9
CONFIDENTIALITY AND NON-DISCLOSURE

9.1 Confidentiality Obligations. At all times during the Term and for a period of [***] years following termination or expiration hereof in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is necessary or reasonably useful for the performance of, or the exercise of such Party's rights under, this Agreement. "**Confidential Information**" means any technical, business, or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information of Third Parties, information relating to the terms of this Agreement, any Collaboration Product (including the Regulatory Documentation and Development Data), any Development or Commercialization of any Collaboration Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Regeneron Know-How (which shall be the Confidential Information of Regeneron) and Alnylam Know-How (which shall be the Confidential Information of Alnylam), as applicable), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, during the Term, (a) all Regulatory Documentation owned by the Lead Party pursuant to Section 3.6.1(b) ("**Product Regulatory Documentation**") shall be deemed to be the Confidential Information of the Lead Party, and the Lead Party shall be deemed to be the disclosing Party and the Participating Party shall be deemed to be the receiving Party with respect thereto, (b) all Information Controlled by a Party that is specifically and solely related to Product-Specific Factors ("**Product-Specific Information**") shall be deemed to be the Confidential Information of both Parties, and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto, [***]. For purposes of this Agreement, all confidential information related to the Target Program or any Collaboration Products disclosed by a Party under the terms of the Master Agreement is hereby deemed to be the Confidential Information of such Party and will be treated as if disclosed hereunder and subject to the terms of this Agreement; provided that Product Regulatory Documentation, Product-Specific Information and Joint Collaboration IP shall be subject to the immediately preceding sentence, even if disclosed under the terms of the Master Agreement. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 9.1 with respect to any Confidential Information shall not include any information that:

9.1.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party or any of its Affiliates or any Person to whom the receiving Party provided such information;

9.1.2 can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality to the disclosing Party with respect to such information; provided that the foregoing exception shall not apply with respect to Product Regulatory Documentation, Product-Specific Information or Joint Collaboration IP;

9.1.3 is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality to the disclosing Party with respect to such information; or

9.1.4 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; provided that the foregoing exception shall not apply with respect to Product Regulatory Documentation, Product-Specific Information or Joint Collaboration IP.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

9.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

9.2.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; provided, however, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order or required to be disclosed be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by Applicable Law; and provided further that the Confidential Information disclosed in response to such court or governmental order or as required by Applicable Law shall be limited to that information which is legally required to be disclosed in response to such court or governmental order or by such Applicable Law;

9.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for INDs or Regulatory Approval pursuant to the terms of this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

9.2.3 made by the receiving Party or its Affiliates or Sublicensees to its or their attorneys, auditors, advisors, consultants, contractors, existing or prospective collaboration partners, licensees, sublicensees, or acquirers as may be necessary or reasonably useful in connection with, or to its or their existing or prospective investors, lenders or financing partners as may be necessary in connection with, the Exploitation of any Collaboration Product, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement, or to potential or actual investors, lenders, financing partners, collaboration partners, licensees, sublicensees, or acquirers as may be necessary or reasonably useful in connection with their evaluation of such potential or actual transaction; provided, however, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this ARTICLE 9 (but with respect to disclosing the terms of this Agreement to existing or prospective non-strategic financial investors, lenders or financing partners, then with a duration of confidentiality as appropriate that is no less than [***] from the date of disclosure);

9.2.4 with respect to Joint Collaboration IP made by either Party or its Affiliates as may be necessary or reasonably useful in connection with the Exploitation of any product so long as such Party or its Affiliates is not in violation of this Agreement, including under Section 6.1, Section 6.2 and Section 6.7; or

9.2.5 required under an In-License; provided that the recipient is subject in writing to substantially the same confidentiality obligations as the Parties.

9.3 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 9.3 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

9.4 Public Announcements. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which

the securities of the disclosing Party are listed (or to which an application for listing has been submitted) and except that a Party may, once a press release or other public written statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other public written statement without the further approval of the other Party. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Notwithstanding the foregoing, the Lead Party, its Affiliates and its and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding any Collaboration Product; provided (a) such disclosure is subject to the provisions of this ARTICLE 9 with respect to the Participating Party's Confidential Information and (b) the Lead Party shall not use the name of the Participating Party (or insignia, or any contraction, abbreviation or adaptation thereof) without the Participating Party's prior written permission. Notwithstanding the foregoing, (x) prior to either Party exercising its Opt-Out Right, to the extent that such disclosure describes the commencement or "top-line" results of Clinical Trials of a Collaboration Product, the achievement of any material Development events with respect to a Collaboration Product or the filing for or receipt of Regulatory Approval with respect to the Collaboration Product in the Territory (each, a "**Major Event**"), at the Participating Party's request the Lead Party will make such disclosure or issue such press release jointly with the Participating Party, and (y) after either Party has exercised its Opt-Out Right, the Lead Party will consider in good faith any request by the Participating Party to issue a joint press release or public disclosure with the Participating Party relating to a Major Event. Prior to making any public disclosure, to the extent practicable, the Lead Party shall provide the Participating Party with a draft of such proposed disclosure for the Participating Party's review and comment, which shall be considered in good faith by the Lead Party. Unless and until a Party has exercised its Opt-Out Right, such draft shall be provided to the Participating Party at least [***] Business Days (or, to the extent faster timely disclosure of a material event is required by Applicable Law or stock exchange or stock market rules, such shorter period of time sufficiently in advance of the disclosure so that the Participating Party will have the opportunity to comment upon the disclosure and the Lead Party will be able to comply with its obligations as required by Applicable Law or stock exchange or stock market rules) prior to making any such disclosure, for the Participating Party's review and comment, which shall be considered in good faith by the Lead Party. If a Party has exercised its Opt-Out Right, such draft shall be provided to the Participating Party at least [***] (or, to the extent faster timely disclosure of a material event is required by Applicable Law or stock exchange or stock market rules, such shorter period of time sufficiently in advance of the disclosure so that the Participating Party will have the opportunity to comment upon the disclosure and the Lead Party will be able to comply with its obligations as required by Applicable Law or stock

exchange or stock market rules) prior to making any such disclosure, for the Participating Party's review and comment, which shall be considered in good faith by the Lead Party. Without limiting the foregoing, the Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party shall be entitled to make such filings, except that the Parties shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with Applicable Law. The filing Party shall provide the non-filing Party with an advance copy of this Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider the non-filing Party's timely comments thereon and cooperate with such non-filing Party in seeking such confidential treatment and, upon the written request of the non-filing Party, shall request an appropriate extension of the term of the confidential treatment period. For the avoidance of doubt, each Party shall be responsible for its own legal and other costs in connection with any filing governed by the terms of this Section 9.4.

9.5 Publications. As between the Parties, the Lead Party shall have the sole right, in consultation with the Participating Party, to issue and control all publications in scientific journals and make scientific presentations related to any Collaboration Product. The Lead Party will consider in good faith any request by the Participating Party to publish Development results related to any Collaboration Product; provided that the Participating Party has not exercised its Opt-Out Right. The Lead Party shall provide the Participating Party with an advance copy of the proposed publication, and the Participating Party shall then have [***] days prior to submission for any publication in which to comment and to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Information belonging in whole or in part to the Participating Party or that is the Confidential Information of the Participating Party. If the Participating Party informs the Lead Party that such publication, in the Participating Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to the Participating Party, or on any Information that is Confidential Information of the Participating Party, the Lead Party shall delay or prevent such publication as follows: (i) with respect to a patentable invention, such publication shall be delayed sufficiently long (not to exceed [***] days) to permit the timely preparation and filing of a patent application; and (ii) with respect to Information that is Confidential Information of such Participating Party (other than the results of a Clinical Trial or any Product Regulatory Information), such Information shall be deleted from the publication. The Lead Party will also consider in good faith any other comments of the Participating Party. Any publication shall include recognition of the contributions of the Participating Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

9.6 Return of Confidential Information. Upon the effective date of the expiration pursuant to Section 12.1(a) or termination of this Agreement for any reason, either Party may request

in writing, and the other Party shall either, with respect to Confidential Information to which such other Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, however, the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 9.1.

9.7 Confidential Information that Relates to Multiple Programs. Notwithstanding the foregoing provisions of this ARTICLE 9, if (a) there is Confidential Information of a Party hereunder that is also Confidential Information of such Party under the Master Agreement, a License Agreement or another Co-Co Collaboration Agreement (as "Confidential Information" is defined in such other agreement), and (b) there is a conflict between the provisions of this Agreement, on the one hand, and the Master Agreement, a License Agreement or Co-Co Collaboration Agreement, as applicable, on the other hand, with respect to the disclosure and non-use of such Confidential Information, the provisions of the agreement that provides the most protection of a Party's Confidential Information (i.e., Regeneron, with respect to Regeneron's Confidential Information, and Alnylam, with respect to Alnylam's Confidential Information) shall control.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Alnylam and Regeneron each represents and warrants to the other, as of the Effective Date, as follows:

10.1.1 Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

10.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party (or any of its Affiliates) is bound, (c) any requirement of any

Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party (or any of its Affiliates).

10.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

10.1.4 No Debarment. Neither it nor any of its Affiliates, nor its or their respective employees, have been debarred or are subject to debarment.

10.1.5 No Inconsistent Obligation. It (and each of its Affiliates) is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

10.1.6 Governmental Consents. Except as set forth in Section 4.9 of the Master Agreement, no authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or will be necessary to be obtained by such Party for, or in connection with, the transaction contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as set forth in Section 3.6.

10.1.7 Third Party Consents. Except as set forth in Section 4.9 of the Master Agreement, it has obtained all necessary authorizations, consents and approvals of any Third Party that is required to be obtained by it as of the Effective Date for, or in connection with, the transaction contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as set forth in Section 3.6.

10.2 Additional Representations, Warranties and Covenants of Alnylam. Except as provided in **Schedule 10.2**, Alnylam further represents and warrants to Regeneron, as of the Effective Date, and covenants, as follows:

10.2.1 Alnylam is the sole and exclusive owner of, or otherwise Controls pursuant to an Existing Alnylam In-License (or will Control pursuant to an Additional Alnylam In-License at such time that such Additional Alnylam In-License is included as an Existing Alnylam In-License pursuant to Section 6.5.2), the Alnylam Background Technology, and all of the Alnylam Background Technology licensed to Regeneron hereunder that is solely and exclusively owned by Alnylam is free and clear of liens, charges or encumbrances other than licenses and rights granted to Third

Parties that are not inconsistent with the rights and licenses granted to Regeneron under this Agreement.

10.2.2 Alnylam has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Alnylam Background Technology to grant the licenses to such Alnylam Background Technology granted to Regeneron pursuant to this Agreement.

10.2.3 To Alnylam's Knowledge, (x) **Schedule 1.17** sets forth a complete and accurate list of the Alnylam Core Technology Patents and (y) **Schedule 1.28** sets forth a complete and accurate list of the Alnylam Product-Specific Patents. **Schedule 1.17** indicates whether each Alnylam Core Technology Patent is (a) owned exclusively by Alnylam or any of its Affiliates, (b) owned jointly by Alnylam or any of its Affiliates, on the one hand, and one or more Third Parties, on the other hand, or (c) licensed to Alnylam or any of its Affiliates. For each Alnylam Core Technology Patent that is owned, but not owned exclusively, by Alnylam or any of its Affiliates, or that is licensed to Alnylam or any of its Affiliates, **Schedule 1.17** identifies the Third Party owner(s) and, if applicable, the Existing Alnylam In-License pursuant to which Alnylam Controls such Alnylam Core Technology Patent. For each Alnylam Core Technology Patent that is licensed, but not exclusively licensed, to Alnylam, **Schedule 1.17** indicates the non-exclusive nature of the license. Alnylam or one of its Affiliates is the sole and exclusive owner of all Alnylam Core Technology Patents identified on **Schedule 1.17** as being owned exclusively by Alnylam or any of its Affiliates and Alnylam Controls, pursuant to an Existing Alnylam In-License, all other Patent Rights identified on such schedules. Alnylam or one of its Affiliates is the sole and exclusive owner of all Alnylam Product-Specific Patents identified on **Schedule 1.28**.

10.2.4 All Alnylam Patents for which Alnylam or any of its Affiliates controls prosecution and maintenance (the "**Alnylam Managed Patents**") are filed and maintained properly and correctly and, to Alnylam's Knowledge, all applicable fees have been paid on or before any final due date for payment. Alnylam has complied with all Applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Alnylam Managed Patents.

10.2.5 To Alnylam's Knowledge, the Alnylam Patents are, or, upon issuance, will be, valid and enforceable Patent Rights.

10.2.6 [***]

10.2.7 [***]

10.2.8 Alnylam has obtained from all inventors of Alnylam Background Technology that is indicated on **Schedule 1.17** or **Schedule 1.28** as being solely and exclusively owned by Alnylam or any of its Affiliates valid and enforceable agreements that have assigned to Alnylam or

its Affiliate each such inventor's entire right, title and interest in and to all such Alnylam Background Technology.

10.2.9 To Alnylam's Knowledge, the Exploitation of the Alnylam Background Technology with respect to the Collaboration Products as contemplated under this Agreement, (a) does not and will not infringe any issued Patent Right of any Third Party or misappropriate any Information or other intellectual property of any Third Party and (b) will not infringe the claims of any published Third Party patent application when and if such claims were to issue in their current form.

10.2.10 [***]

10.2.11 **Schedule 1.107** sets forth a complete and accurate list of all agreements between Alnylam and a Third Party entered into prior to the Effective Date pursuant to which Alnylam Controls (or will Control pursuant to an Additional Alnylam In-License at such time that such Additional Alnylam In-License is included as an Existing Alnylam In-License pursuant to Section 6.5.2) Information or Patent Rights that are necessary or reasonably useful to the practice of the Alnylam Background Technology as contemplated in this Agreement. Alnylam has provided Regeneron with true and complete copies of all Existing Alnylam In-Licenses and Additional Alnylam In-Licenses. [***]

10.2.12 To Alnylam's Knowledge, no Existing Alnylam CMO has made or generated any improvement, discovery or Information, patentable or otherwise, in the course of performing services for Alnylam or any of its Affiliates with respect to any siRNA drug product that is (a) necessary to establish and validate a manufacturing process for such siRNA drug product at another Existing Alnylam CMO (or another Third Party contract manufacturer, as the case may be) and (b) not owned or Controlled by Alnylam. [***]

10.2.13 Part 1 of **Schedule 10.2.13** sets forth a true, correct and complete list of all [***]. Part 2 of **Schedule 10.2.13** sets forth a true, correct and complete description of all terms and conditions [***].

10.3 Additional Representations and Warranties of Regeneron. Except as provided in **Schedule 10.3**, Regeneron further represents and warrants to Alnylam, as of the Effective Date, as follows:

10.3.1 Neither Regeneron nor any of its Affiliates has granted any Third Party, and neither Regeneron nor any of its Affiliates is under any obligation to grant any Third Party, any right to Exploit any Collaboration Product in the Territory, except as set forth in Section 6.7.3.

10.3.2 To Regeneron's Knowledge, **Schedule 1.258** sets forth a complete and accurate list of the Regeneron Product-Specific Patents. Regeneron or one of its Affiliates is the sole and exclusive owner of all Regeneron Product-Specific Patents identified on **Schedule 1.258**. Regeneron has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Regeneron Product-Specific Patents and Regeneron Product-Specific Know-How within the Regeneron Background Technology to grant the licenses to such Regeneron Product-Specific Patents and Regeneron Product-Specific Know-How granted to Alnylam pursuant to this Agreement.

10.3.3 All Regeneron Product-Specific Patents for which Regeneron or any of its Affiliates controls prosecution and maintenance (the "**Regeneron Managed Patents**") are filed and maintained properly and correctly and, to Regeneron's Knowledge, all applicable fees have been paid on or before any final due date for payment. Regeneron has complied with all Applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Regeneron Managed Patents.

10.3.4 To Regeneron's Knowledge, the Regeneron Product-Specific Patents are, or, upon issuance, will be, valid and enforceable Patent Rights.

10.3.5 Neither Regeneron nor any of its Affiliates has granted any Third Party, and neither Regeneron nor any of its Affiliates is under any obligation to grant any Third Party any rights under Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents or otherwise assign to any Third Party any Information or Patent Rights that would otherwise constitute Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents.

10.3.6 Regeneron has obtained from all inventors of Regeneron Product-Specific Patents within the Regeneron Background Technology that is indicated on **Schedule 1.258** as being solely and exclusively owned by Regeneron or any of its Affiliates valid and enforceable agreements that have assigned to Regeneron or its Affiliate each such inventor's entire right, title and interest in and to all such Regeneron Product-Specific Patents within the Regeneron Background Technology.

10.3.7 There is no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to Regeneron's Knowledge, threatened against Regeneron or any of its Affiliates or (b) judgment or settlement against or owed by Regeneron or any of its Affiliates, in each case ((a) and (b)), in connection with the Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents within the Regeneron Background Technology, including any claim alleging that (x) the issued patents in such Regeneron Product-Specific Patents are invalid or unenforceable, or the patent applications in such Regeneron Product-Specific Patents will, upon issuance, be invalid or

unenforceable or (y) the conception, development, reduction to practice, disclosing, copying, making, assigning or licensing of such Regeneron Product-Specific Know-How or the practice thereof as contemplated in this Agreement infringes or would infringe any Patent Rights of any Person or misappropriates or would misappropriate any Information or other intellectual property right of any Person.

10.3.8 Regeneron has provided Alnylam with true and complete copies of all Existing Regeneron In-Licenses (subject to any applicable confidentiality restrictions). There are no terms or conditions in any Existing Regeneron In-License or Existing Regeneron Third Party Agreement that (a) would prevent Alnylam from exercising its rights under this Agreement with respect to the prosecution, maintenance, enforcement or defense of any Product-Related IP; (b) would require Regeneron or any of its Affiliates to grant any Third Party rights under Regeneron Product-Specific Know-How or Regeneron Product-Specific Patents or (c) grant to any Third Party contractual exclusivity with respect to the development, manufacture or commercialization of an siRNA Directed to the Target. Neither Regeneron nor its Affiliates are in material breach or default under any Existing Regeneron In-License, nor, to Regeneron's Knowledge, is any counterparty thereto in material breach of any Existing Regeneron In-License, and neither Regeneron nor its Affiliates have received any written notice of breach or default with respect to any Existing Regeneron In-License. The licenses granted to Regeneron or its Affiliates in the Existing Regeneron In-Licenses are in full force and effect and, subject to their terms, are sublicenseable to Alnylam as contemplated by this Agreement. The execution and performance of this Agreement does not constitute a material breach of any Existing Regeneron In-License.

10.3.9 Schedule 10.3.9 sets forth a true, correct and complete list of all [***] pursuant to this Agreement.

10.4 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENT RIGHTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. FOR THE AVOIDANCE OF DOUBT, THE FOREGOING IS NOT INTENDED TO LIMIT IN ANY WAY ANY EXPRESS REPRESENTATIONS OR WARRANTIES MADE BY EITHER PARTY UNDER THE MASTER AGREEMENT, ANY LICENSE AGREEMENT OR ANY OTHER CO-CO COLLABORATION AGREEMENT.

10.5 Additional Covenants.

10.5.1 Compliance. Each Party and its Affiliates and Sublicensees shall conduct the Development, Manufacture and Commercialization of the Collaboration Products in material accordance with all Applicable Laws and industry standards, including, to the extent applicable, current governmental regulations concerning good laboratory practices, good clinical practices and good manufacturing practices. Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

10.5.2 Debarment. Neither Party nor any of its Affiliates will use in any capacity, in connection with the performance of its obligations under this Agreement, any Person that has been debarred. Each Party agrees to inform the other Party in writing promptly if it learns that it or any Person that is performing activities in connection with activities under this Agreement is debarred or is subject to debarment, or, to the notifying Party's Knowledge, if debarment of the notifying Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the performance of its obligations under this Agreement, is threatened.

ARTICLE 11
INDEMNITY

11.1 Indemnity.

11.1.1 Alnylam's Indemnification Obligations. Alnylam shall defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees and agents ("**Regeneron Indemnitees**") from and against all loss, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs payable to a Third Party (collectively, "**Damages**"), incurred by any Regeneron Indemnitee as a result of a Third Party's claim, action, suit, settlement, or proceeding (each, a "**Claim**") against a Regeneron Indemnitee to the extent such Claim arises out of or results from:

(a) the gross negligence, recklessness, willful misconduct, or intentional wrongful acts or omissions of Alnylam or any of its Affiliates (or its or their respective agents, contractors, Sublicensees, partners, representatives or other Persons working on its or their behalf) in its or their respective performance under this Agreement, the Supply Agreement (if any) or the Quality Agreement (if any), including (i) any activities under any Development Plan and Budget or the Manufacture and supply of (A) the Early Stage Supply Requirements and (B) if applicable, Late Stage Supply Requirements, (ii) Alnylam's performance of Alnylam Specific Activities, and (iii) if Alnylam is the Lead Party, in connection with the Exploitation of any Collaboration Product by or on behalf of Alnylam;

(b) a breach by Alnylam of this Agreement (including the inaccuracy of any representation or warranty made by Alnylam in this Agreement), the Supply Agreement (if any) or the Quality Agreement (if any);

(c) if Regeneron exercises its Opt-Out Right, the Exploitation of any Collaboration Product by or on behalf of Alnylam pursuant to this Agreement from and after the Opt-Out Date (excluding any activities with respect to such Exploitation performed by or on behalf of Regeneron);

(d) any amounts payable to a Third Party under an Alnylam In-License based on a sharing with such Third Party of (i) amounts paid to Alnylam by Regeneron pursuant to this Agreement or (ii) any profits or losses received by Alnylam pursuant to this Agreement or (iii) any Third Party Transaction Proceeds (e.g., any amounts payable to a Third Party that constitute a share of any sublicensing income); or

(e) the Excluded Agreements or any of the intellectual property licensed thereunder (including infringement or misappropriation thereof) with respect to the activities hereunder;

except, in the case of (a), (b) and (c), for those Damages for which Regeneron has an obligation to indemnify Alnylam pursuant to Section 11.1.2(a) or Section 11.1.2(b), as to which Damages each Party shall indemnify the other Party and the Regeneron Indemnitees or Alnylam Indemnitees, as applicable, to the extent of its respective liability for such Damages.

11.1.2 Regeneron's Indemnification Obligations. Regeneron shall defend, indemnify and hold harmless Alnylam, its Affiliates and its and their respective officers, directors, employees and agents ("**Alnylam Indemnitees**") from and against all Damages incurred by any Alnylam Indemnitee as a result of a Claim against an Alnylam Indemnitee to the extent such Claim arises out of or results from:

(a) the gross negligence, recklessness, willful misconduct, or intentional wrongful acts or omissions of Regeneron or any of its Affiliates (or its or their respective agents, contractors, Sublicensees, partners, representatives or other Persons working on its or their behalf) in its or their respective performance under this Agreement, including (i) any activities under any Development Plan and Budget and, if applicable, the Manufacture and supply of the Late Stage Supply Requirements, and (ii) if Regeneron is the Lead Party, in connection with the Exploitation of any Collaboration Product by or on behalf of Regeneron;

(b) a breach by Regeneron of this Agreement (including the inaccuracy of any representation or warranty made by Regeneron in this Agreement);

(c) if Alnylam exercises its Opt-Out Right, the Exploitation of any Collaboration Product by or on behalf of Regeneron pursuant to this Agreement from and after the Opt-Out Date (excluding any activities with respect to such Exploitation performed by or on behalf of Alnylam); or

(d) any amounts payable to a Third Party under a Regeneron In-License based on a sharing with such Third Party of (i) amounts paid to Regeneron by Alnylam pursuant to this Agreement or (ii) any profits or losses received by Regeneron pursuant to this Agreement or (iii) any Third Party Transaction Proceeds (e.g., any amounts payable to a Third Party that constitute a share of any sublicensing income);

except, in the case of (a), (b) and (c), for those Damages for which Alnylam has an obligation to indemnify Regeneron pursuant to Section 11.1.1(a) or Section 11.1.1(b), as to which Damages each Party shall indemnify the other Party and the Regeneron Indemnitees or Alnylam Indemnitees, as applicable, to the extent of its respective liability for such Damages.

11.1.3 Shared Damages. With respect to any Damages arising out of any Claim brought against any Alnylam Indemnitee or Regeneron Indemnitee resulting from (a) the Exploitation of any Collaboration Product pursuant to this Agreement prior to the date on which a Party exercises its Opt-Out Right or (b) the conduct of a Clinical Trial of Collaboration Product hereunder that is ongoing as of the date on which a Party exercises its Opt-Out Right and for which the Opt-Out Party is required to continue to co-fund Development Costs in Section 3.5.7 (as such Clinical Trial is set forth in the Development Plan and Budget as of the date of the exercise of such Opt-Out Right), in each case, including personal injury or death resulting from use of any Collaboration Product and any Claim alleging that the Exploitation of a Collaboration Product pursuant to this Agreement infringed a Patent Right of a Third Party, but for which (i) Alnylam is not otherwise obligated to indemnify a Regeneron Indemnitee pursuant to Section 11.1.1(a), 11.1.1(b), or 11.1.1(d), and (ii) Regeneron is not otherwise obligated to indemnify an Alnylam Indemnitee pursuant to Section 11.1.2(a), 11.1.2(b) or 11.1.2(d) (such Claim, a "**Shared Claim**" and such Damages, "**Shared Damages**"), each Party shall indemnify the other Party for fifty percent (50%) of the Shared Damages and during the Term the Shared Damages shall be shared by the Parties as Other Shared Expenses.

11.2 Indemnity Procedure.

11.2.1 Notification. The Party entitled to indemnification under Section 11.1.1 or Section 11.1.2 (an "**Indemnified Party**") shall notify the Party potentially responsible for such indemnification (the "**Indemnifying Party**") within five (5) Business Days of becoming aware of any Claim asserted or threatened in writing against the Indemnified Party that could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such

notice shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that such failure materially prejudices the Indemnifying Party. Each Party shall promptly notify the other Party in writing of any Shared Claim of which such Party becomes aware.

11.2.2 Control of Defense. If the Indemnifying Party elects in writing to the Indemnified Party that it will assume control of the defense of such Claim, the Indemnifying Party shall have the right to defend such Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless the Indemnified Party consents to such compromise or settlement, which consent shall not be unreasonably withheld, conditioned or delayed, and which consent shall be deemed given with respect to any Damages relating solely to the payment of money damages if such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim. If the Indemnifying Party does not elect to assume control of the defense of such Claim within [***] days of its receipt of notice thereof, or if the Indemnifying Party elects in writing to the Indemnified Party to cease maintaining control of the defense of such Claim, the Indemnified Party shall have the right upon at least [***] Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such Claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such Claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such Claim. The Indemnified Party may not compromise or settle such Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

11.2.3 Indemnified Party's Participation. The Indemnified Party shall cooperate with the Indemnifying Party in, and may participate in, but not control, any defense or settlement of any Claim controlled by the Indemnifying Party pursuant to this Section 11.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that, if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party, on the one hand, and the Indemnified Party and Alnylam Indemnitees or Regeneron Indemnitees, as applicable, on the other hand, (a) if a Claim is a Shared Claim, such costs and expense shall be Other Shared Expenses and (b) if a Claim is not a Shared Claim, the Indemnifying Party shall bear such costs and expenses.

11.2.4 Defense Procedures For Shared Claims. The indemnification procedures in this Section 11.2 shall apply to Shared Claims pursuant to Section 11.1.3; provided that the Lead

Party shall be deemed to be the Indemnifying Party and the Participating Party shall be deemed to be the Indemnified Party. For clarity, such allocation of roles shall only apply to the procedures described in this Section 11.2, and the cross-indemnity described in Section 11.1.3 shall continue to apply.

11.2.5 Expenses. With respect to Claims under Section 11.1.1 or Section 11.1.2, the costs and expenses, including fees and disbursements of counsel, (a) incurred by the Indemnifying Party, shall be the responsibility of the Indemnifying Party or (b) incurred by the Indemnified Party pursuant to the proviso in Section 11.2.3 shall be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party or the Alnylam Indemnitees or Regeneron Indemnitees, as applicable. With respect to Claims under Section 11.1.3, the costs and expenses, including fees and disbursements of counsel, incurred by either Party, shall be Other Shared Expenses.

11.3 Insurance. During the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by Applicable Law, each of Regeneron and Alnylam shall (a) use Commercially Reasonable Efforts to procure and maintain appropriate commercial general liability and product liability insurance in an [***] or (b) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Alnylam, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Section 11.1 or otherwise. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until (a) if neither Party has exercised its Opt-Out Right, the first date on which neither the Lead Party nor any of its Affiliates or its or their Sublicensees is Developing any Collaboration Products for, or Commercializing such Collaboration Products in, the Territory under this Agreement, with the normal pauses or gaps between or following Clinical Trials or other studies for the analysis of data, preparation of reports and design of future Clinical Trials or preparation of Drug Approval Applications and other

customary Development functions not constituting Clinical Trials not constituting cessation of Development; or (b) if a Party has exercised its Opt-Out Right, the date of expiration of the last Royalty Term for the last Collaboration Product (such period, the "**Term**").

12.2 Termination for Material Breach. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") has materially breached this Agreement, the Supply Agreement (if any) or the Quality Agreement (if any) in a manner that fundamentally frustrates the value or essential characteristics of the transactions contemplated by this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "**Default Notice**"). If the Breaching Party does not dispute that it has committed such a material breach under this Agreement, the Supply Agreement (if any) or the Quality Agreement (if any) that results in the Non-Breaching Party having a right to terminate this Agreement, then if the Breaching Party fails to cure such breach, or fails to take steps as would be considered reasonable to effectively cure such breach, within ninety (90) days after receipt of the Default Notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party disputes that it has committed a material breach under this Agreement, the Supply Agreement (if any) or the Quality Agreement (if any) that results in the Non-Breaching Party having a right to terminate this Agreement, the dispute shall be resolved pursuant to Section 13.5. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to have materially breached in a manner that fundamentally frustrates the value or essential characteristics of the transactions contemplated by this Agreement (an "**Adverse Ruling**"), then if the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within ninety (90) days after such ruling, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; provided that if such compliance cannot be fully achieved within such ninety (90)-day cure period, then such cure period will be extended for a period of up to sixty (60) additional days (for a total cure period of one hundred fifty (150) days) if the Breaching Party prepares and provides to the Non-Breaching Party a reasonable written plan for curing such material breach and uses commercially reasonable efforts to cure such material breach in accordance with such written plan, and if such material breach is not cured within such one hundred fifty (150)-day period, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

12.3 Termination for Insolvency. In the event that either Party (or its ultimate parent) (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within sixty (60) days of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other

Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

12.4 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Regeneron or Alnylam are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

12.5 Additional Lead Party Termination Right. If a Party exercises its Opt-Out Right, and thereafter, the Lead Party (which may be the New Lead Party, if applicable), desires to terminate its obligations with respect to Development and Commercialization of the Collaboration Products, it shall so notify the Participating Party and thereafter: (a) the Lead Party's obligation to use Commercially Reasonable Efforts to Develop and Commercialize Collaboration Products shall terminate, (b) each Party's obligations under Section 6.7.1 shall terminate, (c) the Parties shall cooperate in good faith to license, sell or otherwise grant or transfer to a Third Party the right to further Develop or Commercialize the Collaboration Products (but excluding any Proprietary Unlicensed Components); provided that the Lead Party shall control the process of licensing, selling or otherwise granting or transferring such right to further Develop or Commercialize the Collaboration Products and shall have final say with respect to entering into a transaction with a Third Party with respect thereto, and (d) the Parties shall share the proceeds of any such transaction as if they were Third Party Transaction Proceeds at the Third Party Transaction Proceeds Percentage and negotiate in good faith the terms of termination of this Agreement to accommodate any such transaction.

12.6 Effects of Termination. In the event of a termination of this Agreement in its entirety by either Party pursuant to Section 12.2 or Section 12.3 (but excluding, for clarity, termination pursuant to Section 12.5), the provisions of **Schedule 12.6(B)** shall apply, unless (a) the terminating

Party is the Lead Party and the Lead Party notifies the Participating Party in writing prior to the effective date of termination that the Lead Party desires for the provisions of **Schedule 12.6(A)** to apply or (b) the Participating Party notifies the Lead Party in writing prior to the effective date of termination that the Participating Party desires for the provisions of **Schedule 12.6(A)** to apply, in which case ((a) or (b)), the provisions of **Schedule 12.6(A)** shall apply.

12.7 Remedies. Except as otherwise expressly provided herein, expiration or termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

12.8 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued (or that may accrue as a result of activities under this Agreement) to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated or by their nature are intended to survive the termination or expiration of this Agreement, including this Section 12.8, 3.4.1 (for the period set forth therein), 3.4.4, 3.6.2 (last sentence only), 4.9.3, 6.1.1 (with respect to any perpetual license following the Royalty Term set forth in Section 6.1.1), 6.1.2 (with respect to any perpetual license following the Royalty Term set forth in Section 6.1.2), 6.1.5 (including the last paragraph of Section 6.1 (i.e., unnumbered paragraph beginning with "Notwithstanding") as applied to Sections 6.1.1, 6.1.2, and 6.1.5 only), 6.2.1(b), 6.2.2(a) (with respect to any perpetual license following the Royalty Term set forth in Section 6.2.2(a)), 6.2.2(b) (with respect to any perpetual license following the Royalty Term set forth in Section 6.2.2(b)) (including the last paragraph of Section 6.2 (i.e., unnumbered paragraph beginning with "Notwithstanding") as it applies to Sections 6.2.1(b), 6.2.2(a) and 6.2.2(b) only), 6.4, 6.6, 7.1 through 7.2 (to the extent such payments have accrued but not been paid), 7.5, 7.6, 7.8, 7.9 (for the period set forth therein), 7.10 (for the three (3)-year period following expiration or termination of this Agreement), 7.11, 8.1.1, 8.1.2, 8.1.3, 8.2.7, 8.7.2, 9.1 (for the period set forth therein), 9.2 (for the period set forth in Section 9.1), 9.3, 9.6, 10.4, 12.4, 12.6 (including, for clarity, **Schedule 12.6(A)** and **Schedule 12.6(B)**, as applicable), 12.7; ARTICLES 1 (to the extent necessary to interpret the remaining surviving provisions, and including, for clarity, the corresponding schedules, as applicable), 11 and 13; and **Schedules 1** and **2** of this Agreement shall survive the termination or expiration of this Agreement for any reason.[46]

[46] Note to Draft: Survival sections to be updated based on which provisions are ultimately included in the Agreement.

ARTICLE 13
MISCELLANEOUS

13.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within seven (7) Business Days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

13.2 Assignment. Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party may make such an assignment without the other Party's consent to its Affiliate or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all of such Party's business, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. With respect to an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section 13.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Alnylam or Regeneron, as the case may be. In the event either Party seeks and obtains the other Party's consent to assign or delegate its rights or obligations to another Party, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

13.3 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

13.4 Governing Law, Jurisdiction and Service.

13.4.1 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Except for (a) JSC Disputes, which are governed by Section 2.6.3, (b) Financial Disputes, which are governed by Section 13.5, (c) Expedited Matters, which are governed by **Schedule 1**, or (d) Expert Disputes, which are governed by **Schedule 2**, each Party acknowledges and agrees that it must commence any action, suit or proceeding arising out of or in connection with this Agreement (other than appeals therefrom) in the jurisdiction where the other Party is incorporated or has its principal place of business, and each Party hereby waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in courts in such jurisdiction. The Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, with respect to any Legal Dispute, subject, however, to this Section 13.4.1 and Section 13.9.

13.4.2 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 13.6.2 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

13.5 Dispute Resolution.

13.5.1 Except as provided in Section 13.9 or the last sentence of this Section 13.5.1, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, including Financial Disputes, Expedited Matters, Legal Disputes and Expert Disputes, it shall be resolved pursuant to this Section 13.5.

Notwithstanding the foregoing, the Parties shall resolve all JSC Disputes solely pursuant to Section 2.6.3 and this Section 13.5 does not apply to any such JSC Disputes.

13.5.2 Either Party may require that any dispute, other than JSC Disputes (which are governed by Section 2.6.3), Expedited Matters (which are governed by **Schedule 1** and are referred to Executive Officers pursuant to the terms thereof) and Expert Disputes (which are governed by **Schedule 2**), be submitted to the Executive Officers for resolution by providing written notice to the other Party formally requesting that the dispute be resolved by the Executive Officers and specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. If a dispute is referred to the Executive Officers, then the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within thirty (30) days after receiving written notification of such dispute or such longer period of time as the Executive Officers may agree in writing. Any final decision mutually agreed to by the Executive Officers with respect to a dispute and set forth in writing shall be conclusive and binding on the Parties. If the Executive Officers cannot resolve such dispute within such thirty (30) days or such other period as agreed by the Executive Officers, such dispute will be resolved as follows:

(a) with respect to any Financial Dispute, such Financial Dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Financial Expert**"). The decision of the Financial Expert shall be final and the costs of the Financial Expert shall be borne by the Parties in accordance with such allocation as the Financial Expert shall determine;

(b) with respect to any Expedited Matter, such Expedited Matter shall be resolved pursuant to the provisions of **Schedule 1**;

(c) with respect to any Expert Dispute, such Expert Dispute shall be resolved pursuant to the provisions of **Schedule 2**; and

(d) with respect to all other disputes (but, for clarity, excluding JSC Disputes), including Legal Disputes, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise subject, however, to Section 13.4.1 and Section 13.9.

13.6 Notices.

13.6.1 Notice Requirements. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth at its address specified in Section 13.6.2 and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if

delivered by hand or one (1) Business Day after it is sent via a reputable international overnight courier service. Either Party may change its address by giving notice to the other Party in the manner provided above. This Section 13.6.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

13.6.2 Address for Notice.

If to Regeneron, to:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel

If to Alnylam, to:

Alnylam Pharmaceuticals, Inc.
300 Third Street
Cambridge, Massachusetts 02142
Attention: Legal Department

13.7 Entire Agreement; Amendments.

13.7.1 This Agreement, the Supply Agreement (if any) and the Quality Agreement (if any), and the Master Agreement, together with the schedules attached hereto and thereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement, the Supply Agreement (if any) and the Quality Agreement (if any), or the Master Agreement. In the event of a conflict between the provisions of this Agreement and the Master Agreement with respect to the Target Program (or the Target or Collaboration Products thereunder), the provisions of this Agreement shall control. For the avoidance of doubt, the Parties agree and acknowledge that from and after the Effective Date, there shall be no additional Development, Manufacturing or Commercialization activities with respect to the Target Program or the Exploitation of Collaboration Products pursuant to the Master Agreement.

13.7.2 No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 LIMITATION OF DAMAGES. IN NO EVENT SHALL REGENERON OR ALNYLAM BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 13.8 IS INTENDED TO LIMIT OR RESTRICT (A) LIABILITY FOR BREACH OF SECTION 6.7.1 OR ARTICLE 9 OR (B) THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER AS SET FORTH IN SECTION 11.1 WITH RESPECT TO CLAIMS.

13.9 Equitable Relief.

13.9.1 Each Party acknowledges and agrees that the restrictions set forth in Section 6.7 and ARTICLE 9 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Article may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity.

13.9.2 [***]

13.9.3 Each Party hereby waives any requirement that the other Party, as a condition for obtaining any such relief (a) post a bond or other security or (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 13.9 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

13.10 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

13.11 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

13.12 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.13 Relationship of the Parties. It is expressly agreed that Alnylam, on the one hand, and Regeneron, on the other hand, shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture, or agency. Neither Alnylam, on the one hand, nor Regeneron, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

13.14 Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

13.15 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or schedule shall mean references to such Article, Section or schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

13.16 Schedules. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

13.17 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The

captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

ALNYLAM PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

REGENERON PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

[SIGNATURE PAGE TO CO-CO COLLABORATION AGREEMENT]

Schedule 1

Expedited Dispute Resolution

[***]

Schedule 2

Expert Resolution

[***]

Schedule 1.17

Alnylam Core Technology Patents

Schedule 1.28

Alnylam Product-Specific Patents

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Schedule 1.106

Existing Alnylam CMOs

Schedule 1.107

Existing Alnylam In-Licenses

1. Existing Alnylam In-Licenses:

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Existing Alnylam Third Party Agreements

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Existing Regeneron In-Licenses

Schedule 1.110

Existing Regeneron Third Party Agreements

Schedule 1.165

Manufacturing Cost

[***]

[***]

[Schedule 1.204][47]

[***]

[47] [***].

Schedule 1.258

Regeneron Product-Specific Patents

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Target

Schedule 3.1.9

Permitted Alnylam Third Party Providers

Schedule 3.5.7(a)

[***]

Schedule 5.2.2

Key Terms for Supply of Early Stage Supply Requirements

[***]

Schedule 5.2.3

Certain Supply Requirements if the Lead Party is Manufacturing

[***]

Schedule 7.1.1

Quarterly True-Up Payments

[***]

Schedule 7.2.6

Example of Adjustments for Recoupment of Excess Development Costs.

[***]

Schedule 8.2.1

Filing Countries

[***]

Schedule 10.2

Alnylam Disclosure Schedule[48]

[***]

[48] [***]

Schedule 10.2.13

Certain Obligations under Existing Alnylam In-Licenses

[***]

[***]

Schedule 10.3

Regeneron Disclosure Schedule[49]

[***]

[49] Note to Draft: Any exceptions to be added shall be limited to the exceptions provided in the Program Data Package delivered by Regeneron under the Master Agreement.

Schedule 10.3.9

Certain Payment Obligations under Existing Regeneron In-Licenses

Schedule 12.6(A)

Effects of Termination

[***]

Schedule 12.6(B)

Effects of Termination

[***]

Exhibit 10.4.2

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

LICENSE AGREEMENT

between

ALNYLAM PHARMACEUTICALS, INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of [●], [●]

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LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is made and entered into effective as of [●], **[●]** (the "**Effective Date**") by and between Alnylam Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("**Alnylam**"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York ("**Regeneron**"). Alnylam and Regeneron are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Alnylam and Regeneron entered into that certain Master Agreement, dated as of [_____ __], 2019 (the "**Master Agreement**"), pursuant to which, among other things, Alnylam and Regeneron conducted certain research and development activities with respect to siRNAs Directed to the Target (as hereinafter defined) under a Program (as defined in the Master Agreement) for the Target (the "**Target Program**"); and

WHEREAS, pursuant to the terms of the Master Agreement, the Parties are now obligated to enter into a License Agreement (as defined in the Master Agreement) with respect to the Target Program in order for Licensee to further research, development and commercialization of Collaboration Products Directed to the Target on the terms and subject to the conditions as set forth herein (each initially capitalized term as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**AAA**" has the meaning set forth in **Schedule 1**.

1.2 "**Accounting Standards**" means, with respect to either Party, generally accepted accounting principles as applicable in the United States or International Financial Reporting Standards of the International Accounting Standards Board, in each case, as generally and consistently applied throughout such Party's organization. Each Party shall promptly notify the other Party in writing if such Party changes the Accounting Standards pursuant to which its records are maintained.

1.3 "**Acquired Party**" has the meaning set forth in Section 6.7.2(a).

1.4 "**Acquirer**" has the meaning set forth in Section 6.7.2(a).

1.5 "**Acquiring Party**" has the meaning set forth in Section 6.7.2(a).

1.6 "**Acquisition Product**" has the meaning set forth in Section 6.7.2(a).

1.7 "**Additional Alnylam In-Licenses**" means the agreements identified in Section 2 of [**Schedule 1.67**][1].

1.8 "**Adverse Ruling**" has the meaning set forth in Section 12.2.

1.9 "**Affiliate**" means, with respect to a Person, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person for so long as such Person controls, is controlled by or is under common control with such first Person, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management or policies of such entity.

1.10 "**Agreement**" has the meaning set forth in the preamble hereto.

1.11 "**Alliance Manager**" has the meaning set forth in Section 2.2.

1.12 "**Alnylam**" has the meaning set forth in the preamble hereto.

1.13 ["**Alnylam Cost Report**" has the meaning set forth in Section 7.3.][2]

[1] Note to Draft: If Alnylam is Licensor, then replace bracketed "**Schedule 1.67**" with "**Schedule 1.69**".

[2] Note to Draft: Delete this definition if Alnylam is Licensee.

1.14 ["**Alnylam Delivery Patents**" has the meaning set forth in Section 8.2.4.][3]

1.15 ["**Alnylam Manufacturing Technology**" means Licensor Technology relating to the Manufacturing Process of a Collaboration Product that is Controlled by Licensor or its Affiliates during the Term.][4]

1.16 "**Alnylam siRNA Platform**" means [_____][5] Background Technology that relates generally to Alnylam's siRNA platform and is not primarily related to any Collaboration Product.

1.17 ["**Alnylam Specific Activities**" means [***].

1.18 ["**Alnylam Specific Activities Costs**" means the Out-of-Pocket Costs and Development FTE Costs incurred by Licensor in accordance with the plan and budget agreed to by the Parties pursuant to Section 3.1.4 in connection with any Alnylam Specific Activities, but excluding, in all cases, any such costs with respect to the Ongoing Candidate Discovery Development Activities.][6]

1.19 "**ANDA Act**" has the meaning set forth in Section 8.3.5.

1.20 "**Anticipated IND Submission Date**" means the anticipated date of IND submission to the FDA for the first Collaboration Product, as such date is reasonably determined by Licensee.

1.21 "**API**" means any active pharmaceutical (including biological) ingredient or component (but excluding, for clarity, an adjuvant or excipient).

1.22 "**Applicable Law**" means applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time.

1.23 "**ASO**" means a single-stranded antisense oligonucleotide.

1.24 "**Breaching Party**" has the meaning set forth in Section 12.2.

[3] Note to Draft: Include this definition only if the Target is an Eye Target or CNS Target.

[4] Note to Draft: Delete this definition if Alnylam is Licensee.

[5] Note to Draft: Insert "Licensor" if Alnylam is Licensor, or insert "Licensee" if Alnylam is Licensee.

[6] Note to Draft: Delete this definition if Alnylam is Licensee.

1.25 "**Business Day**" means a day other than a Saturday, Sunday or another day of the week on which commercial banks in New York, New York or Boston, Massachusetts, are authorized or required by Applicable Law to remain closed.

1.26 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.27 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.28 "**Change of Control**" means, with respect to a Party (or its ultimate parent), (a) a merger, acquisition, consolidation or reorganization of such Party (or its ultimate parent) with a Third Party that results in the voting securities of such Party (or its ultimate parent) outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the "beneficial owner" (as such term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder (or, in each case, any successor thereto), except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party (or its ultimate parent), or (c) the sale or other transfer to a Third Party, whether directly or indirectly by a Party or an Affiliate thereof, of all or substantially all of such Party's (or its ultimate parent's) business.

1.29 "**Claim**" has the meaning set forth in Section 11.1.1.

1.30 "**Clinical Data**" means all Information with respect to any Collaboration Product that is made, collected, or otherwise generated under or in connection with Clinical Trials, including any data, reports, and results with respect thereto.

1.31 "**Clinical Trial**" means (a) any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or Registration Enabling Trial, (b) such other tests and studies in human subjects that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Collaboration Product for an indication, including tests or studies that are intended to expand the Product Labeling for such Collaboration Product with respect to such indication and (c) any open label extension study of a Collaboration Product.

1.32 "**Co-Co Collaboration Agreement**" means any Co-Co Collaboration Agreement (as defined in the Master Agreement) that is entered into by the Parties (or their respective Affiliates) pursuant to the Master Agreement.

1.33 "**Collaboration Product**" means any product containing an siRNA Directed to the Target as a Relevant Organ Product that is Developed under and in accordance with the Master Agreement or this Agreement [***].

1.34 "**Combination Product**" means a Collaboration Product that is comprised of or contains an siRNA Directed to the Target as an API together with one or more other APIs and is sold either as (i) a fixed dose, (ii) separate doses in a single package or (iii) separate doses in separate packages but for a single price.

1.35 "**Commercial Supply Requirement**" means the quantities of Collaboration Products that are reasonably required to fulfill requirements for commercial sales in the Territory, and other Commercialization uses with respect to the Collaboration Products in the Territory.

1.36 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Collaboration Product, including activities related to marketing, promoting, distributing, and importing such Collaboration Product, and interacting with Regulatory Authorities regarding any of the foregoing after such Collaboration Product has received Regulatory Approval, including seeking Pricing Approvals, maintaining Regulatory Approvals, conducting Non-Approval Trials, commercial pharmacovigilance and health outcomes research and publishing scientific studies other than in connection with Development. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization.

1.37 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development, Commercialization, or Manufacturing activities with respect to a Collaboration Product by a Party or other applicable activities by a Party hereunder, the carrying out of such activities in a diligent manner using efforts and resources [***] devote to products of similar market potential at a similar stage in development or product life, taking into account all scientific, commercial, and other factors that such Party and its Affiliates would take into account, including issues of safety and efficacy, expected and actual cost and time to develop, expected and actual profitability, expected and actual competitiveness of alternative products (including generic

products) in the marketplace, the nature and extent of expected and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected likelihood of regulatory approval, the expected and actual reimbursability and pricing, and the expected and actual amounts of marketing and promotional expenditures required, [***], or (b) payable to such Party by the other Party under this Agreement or the Master Agreement, and provided that, for purposes of determining whether a Party's activities constitute "Commercially Reasonable Efforts," any products of such Party or its [***].

1.38 "**Competing Product**" means, [***].

1.39 "**Competing Product Option**" has the meaning set forth in Section 6.7.2(c).

1.40 "**Competing Product Option Data Package**" means [***].

1.41 "**Competing Program**" has the meaning set forth in Section 6.7.2(a).

1.42 "**Competitive Infringement**" has the meaning set forth in Section 8.3.1.

1.43 "**Confidential Information**" has the meaning set forth in Section 9.1.

1.44 "**Control**" means, with respect to a Party and any item of Information, Regulatory Documentation, material, Patent Right, or other intellectual property right, the possession by such Party or any of its Affiliates of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 6.1 or Section 6.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent Right, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party; provided, that, with respect to rights to any Third Party's Information, Patent Rights or other intellectual property rights that are licensed to, or otherwise obtained by, (a) a Party or its Affiliates pursuant to a Product-Related In-License entered into by such Party or any of its Affiliates after the Effective Date, or (b) Alnylam or its Affiliates pursuant to any Additional Alnylam In-License, such Third Party's Information, Patent Rights or other intellectual property rights shall be deemed not to be under the Control of such Party or its Affiliates, or Alnylam or its Affiliates, respectively, unless and until the agreement pursuant to which such rights are obtained becomes an In-License pursuant to Section 6.5.1(a), Section 6.5.1(b), Section 6.5.1(c) or Section 6.5.2, as applicable.

1.45 "**Core Technology In-License**" means a Product-Related In-License that is not a Product-Specific In-License.

1.46 "**Corporate Names**" means, with respect to Licensor, the Trademarks and logos as Licensor may designate in writing to Licensee from time to time.

1.47 "**Cover**" or "**Covering**" means, as to a product and Patent Rights, that, in the absence of a license granted under, or ownership of, such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights or, as to a pending claim included in such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights if such pending claim were to issue in an issued patent.

1.48 "**Damages**" has the meaning set forth in Section 11.1.1.

1.49 "**Default Notice**" has the meaning set forth in Section 12.2.

1.50 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, Manufacturing scale-up, qualification and validation (but excluding such scale-up, qualification and validation with respect to establishing, or otherwise causing to become operational, any Manufacturing facilities), quality assurance/quality control, Clinical Trials, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing, medical affairs, medical information, medical education, health economic and outcomes research, market research, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. Development also includes the foregoing activities, if any, with respect to any devices (including diagnostics) designed for use with a Collaboration Product. Development does not include conducting Non-Approval Trials. When used as a verb, "Develop" means to engage in Development.

1.51 "**Development Data**" means all non-clinical data and Clinical Data, and other material Information, results, and analyses generated in the course of conducting Development activities under this Agreement.

1.52 [**"Development FTE Cost**" means, for all Alnylam Specific Activities performed by Licensor in accordance with the plan and budget agreed to be the Parties pursuant to Section 3.1.4, the product of (a) the number of FTEs required for such Alnylam Specific Activities and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs without markup.][7]

[7] Note to Draft: Delete this definition if Alnylam is Licensee.

1.53 [“**Development FTE Rate**” means [***] in the Calendar Year ending December 31, 2019, such amount to be adjusted as of January 1, 2020 and annually thereafter by the average of the percentage increases or decreases, if any, in the U.S. CPI for the twelve (12) months ending June 30 of the Calendar Year prior to the Calendar Year for which the adjustment is being made. The Development FTE Rate shall be inclusive of FTE Costs and Expenses. The Parties may determine a separate FTE rate for Development personnel located outside the United States, including an appropriate indexed adjustment mechanism with respect thereto.][8]

1.54 “**Direct Costs**” has the meaning set forth in **Schedule 1.140**.

1.55 “**Directed to**” means, with respect to siRNA and the Target, that such siRNA binds to and interferes with the function of any messenger RNA encoded by the Target. For clarity, in the event an siRNA has been engineered to bind to and interfere with the function of any messenger RNA encoded by a particular gene other than the Target (and has not been engineered to bind to and interfere with the function of any messenger RNA encoded by the Target) but such siRNA additionally binds to or interferes with the function of any messenger RNA encoded by the Target, either directly or indirectly, then such product will not be deemed to be Directed to the Target.

1.56 “**Divestment Period**” has the meaning set forth in Section 6.7.2(b).

1.57 “**Dollars**” or “**$**” means United States Dollars.

1.58 “**Drug Approval Application**” means a New Drug Application (an “**NDA**”) as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application (an “**MAA**”) filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.59 “**Early Stage Supply Requirements**” means the quantities of Collaboration Products (and placebo) that are reasonably required by Licensee to perform its Development activities with respect to Collaboration Product prior to Phase 2 Completion, including pre-clinical, Phase 1 Clinical Trial and Phase 2 Clinical Trial Development activities.

1.60 “**Effective Date**” means the effective date of this Agreement as set forth in the preamble hereto.

[8] Note to Draft: Delete this definition if Alnylam is Licensee.

1.61 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.62 "**European Union**" means the organization of member states of the European Union, as it may be constituted from time to time; provided that for the purposes of this Agreement the United Kingdom and any other country that is a member of the European Union on the Effective Date, shall be deemed to be a member of the European Union even if such country ceases to be a member of the European Union during the term of this Agreement.

1.63 "**Excluded Agreements**" means the agreements set forth on Schedule 1.63.

1.64 "**Excluded Collaboration Technology**" has the meaning set forth in Section 6.7.3(a).

1.65 "**Executive Officer**" means, with respect to Licensor, its Chief Executive Officer, and with respect to Licensee, its Chief Executive Officer.

1.66 "**Existing Alnylam CMOs**" means each of the Third Party contract manufacturers set forth on **Schedule 1.66** and their respective Affiliates, successors and assigns.[9]

1.67 "**Existing Licensee In-Licenses**" means the Third Party agreements identified on **Schedule 1.67**[10][, and any Additional Alnylam In-License included within the definition of Existing Licensee In-Licenses pursuant to Section 6.5.2. For clarity, the Existing Licensee In-Licenses do not include the Excluded Agreements][11].

1.68 "**Existing Licensee Third Party Agreements**" means the agreements identified on **Schedule 1.68**.[12]

[9] Note to Draft: **Schedule 1.66** to include only those Existing Alnylam CMOs under the Master Agreement with respect to the Target Program.

[10] Note to Draft: **Schedule 1.67** to include (i) if Alnylam is Licensee, only those Existing Alnylam In-Licenses under the Master Agreement with respect to the Target Program (either Part 1 or Part 2 of the Schedule of Existing Alnylam In-Licenses to the Master Agreement) or (ii) if Regeneron is Licensee, only those Existing Regeneron In-Licenses under the Master Agreement with respect to the Target Program (either Part 1 or Part 2 of the Schedule of Existing Regeneron In-Licenses to the Master Agreement).

[11] Note to Draft: Delete this bracketed language if Regeneron is Licensee.

[12] Note to Draft: **Schedule 1.68** to include (i) if Alnylam is Licensee, only those Existing Alnylam Third Party Agreements under the Master Agreement with respect to the Target Program or (ii) if Regeneron is Licensee, only those Existing Regeneron Third Party Agreements under the Master Agreement with respect to the Target Program.

1.69 "**Existing Licensor In-Licenses**" means the Third Party agreements identified on **Schedule 1.69**[13][, and any Additional Alnylam In-License included within the definition of Existing Licensor In-Licenses pursuant to Section 6.5.2. For clarity, the Existing Licensor In-Licenses do not include the Excluded Agreements][14].

1.70 "**Existing Licensor Third Party Agreements**" means the agreements identified on **Schedule 1.70**.[15]

1.71 "**Expedited Matter**" has the meaning set forth in **Schedule 1**.

1.72 "**Expert**" has the meaning set forth on **Schedule 2**.

1.73 "**Expert Dispute**" has the meaning set forth in Section 13.5.2(c).

1.74 "**Exploit**" means, with respect to a product, to make, have made, import, use, sell, or offer for sale, including to research (including pre-clinical and clinical research), Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of such product. When used as a noun, "**Exploitation**" means the act of Exploiting a product.

1.75 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.76 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.77 "**Field**" means all human diagnostic, prophylactic, and therapeutic uses.

[13] Note to Draft: **Schedule 1.69** to include (i) if Alnylam is Licensor, only those Existing Alnylam In-Licenses under the Master Agreement with respect to the Target Program (either Part 1 or Part 2 of the Schedule of Existing Alnylam In-Licenses to the Master Agreement) or (ii) if Regeneron is Licensor, only those Existing Regeneron In-Licenses under the Master Agreement with respect to the Target Program (either Part 1 or Part 2 of the Schedule of Existing Regeneron In-Licenses to the Master Agreement).

[14] Note to Draft: Delete this bracketed language if Regeneron is Licensor.

[15] Note to Draft: **Schedule 1.70** to include (i) if Alnylam is Licensor, only those Existing Alnylam Third Party Agreements under the Master Agreement with respect to the Target Program or (ii) if Regeneron is Licensor, only those Existing Regeneron Third Party Agreements under the Master Agreement with respect to the Target Program.

1.78 "**Financial Dispute**" means any dispute related to (a) a Party's method of calculation of Manufacturing Costs, (b) Licensee's method of calculation of any element to determine the Royalties payable, (c) with respect to any In-License that is applicable to products other than the Collaboration Products, the allocation of the In-License Payments with respect to such In-License to the Exploitation of Collaboration Products, (d) the budget for any Alnylam Specific Activities Costs to be negotiated by the Parties, as further described in Section 3.1.4 and (e) any apportionment of revenues from a Combination Product that contains an Unlicensed Component as contemplated by Section 7.1.7.

1.79 "**Financial Expert**" has the meaning set forth in Section 13.5.2(a).

1.80 "**First Commercial Sale**" means, with respect to a Collaboration Product and a country, the first sale by or on behalf of Licensee for monetary value for use or consumption by the end user of such Collaboration Product in such country after Regulatory Approval (other than Pricing Approvals) for such Collaboration Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for such Collaboration Product, such as so-called "treatment IND sales," "named patient sales," "early access programs," "temporary use authorization programs," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.81 ["**FTE**" means a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by Licensor (or any of its Affiliates) and assigned to perform specific Alnylam Specific Activities, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be 1800 hours per year.][16]

1.82 "**FTE Costs and Expenses**" means [***].

[16] Note to Draft: Delete this definition if Alnylam is Licensee.

1.83 "**Generic Product**" means, with respect to a particular Collaboration Product in a particular country in the Territory, any product that (a) is distributed by a Third Party under a separate Drug Approval Application approved by a Regulatory Authority in reliance, in whole or in part, on the Drug Approval Application for such Collaboration Product in such country (or on safety or efficacy data submitted in support of the Drug Approval Application for such Collaboration Product in such country), including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. § 355(b)(2) and 21 U.S.C. § 355(j), respectively), (ii) in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No. 726/2004 that relies for its content on any such provision) or (iii) in any other country or jurisdiction pursuant to an equivalent of such provisions or (b) is substitutable under Applicable Law for such Collaboration Product when dispensed without the intervention of a physician or other health care provider with prescribing authority.

1.84 "**Good Manufacturing Practice**" or "**GMP**" means the current good manufacturing practices applicable from time to time to the manufacturing of a Collaboration Product or any intermediate thereof pursuant to Applicable Law.

1.85 "**In-License**" means (a) any Licensor In-License, and (b) any Licensee In-License.

1.86 "**In-License Payments**" means [***].

1.87 "**IND**" means (a) an investigational new drug application filed with the FDA for authorization to commence Clinical Trials and its equivalent in other countries or regulatory jurisdictions, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.88 "**Indemnified Party**" has the meaning set forth in Section 11.2.1.

1.89 "**Indemnifying Party**" has the meaning set forth in Section 11.2.1.

1.90 "**Indication**" means a separate and distinct disease or medical condition in humans for which a Collaboration Product has received a separate and distinct Regulatory Approval with an approved label claim (in the indication and usage portion of the label) to treat such disease or condition, as applicable. For clarity, (i) moving from one line of therapy to another within an Indication will not be considered to be a new Indication, a non-limiting example of which is moving from second line therapy to first line therapy, (ii) a single Indication would include the primary disease and all variants or sub-divisions or sub-classifications within such primary disease (provided, however, that a variant or sub-division or sub-classification shall be treated as a separate Indication if Regulatory Approval for such variant or sub-division or sub-classification required the

performance of an additional Registration Enabling Trial), including all prophylactic and therapeutic uses, pediatric and adult uses and irrespective of different formulation(s), dosage forms, dosage strengths, or delivery system(s) used, and (iii) obtaining a label expansion for use of the Collaboration Product in combination with another pharmaceutical product in the same Indication for which Regulatory Approval was already obtained, will not be considered to be a new Indication.

1.91 "**Indirect Costs**" has the meaning set forth in **Schedule 1.140**.

1.92 "**Information**" means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and Materials, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays; and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.93 "**Infringement Action**" has the meaning set forth in Section 8.3.2.

1.94 "**Initiation**" or "**Initiate**" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

1.95 "**Joint Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that are conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, jointly by individuals who are employees, agents or consultants of Licensor or its Affiliates or its or their Sublicensees, on the one hand, and individuals who are employees, agents or consultants of Licensee or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a) (the "**Joint Collaboration Patents**"). Joint Collaboration IP also includes any Joint Collaboration IP (as defined in the Master Agreement) from the Master Agreement with respect to the Target Program. Joint Collaboration IP excludes any Licensor Background Technology Improvements and any Licensee Background Technology Improvements.

1.96 "**Joint Collaboration Patents**" has the meaning set forth in the definition of "Joint Collaboration IP."

1.97 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1.

1.98 "**Knowledge**" means, with respect to a Party, the actual knowledge of (i) such Party's internal legal department (including such legal department's intellectual property group), (ii) any employees of such Party who were directly involved in the negotiation of this Agreement with the other Party or who were directly involved in the preparation of such Party's Program Data Package (as defined in the Master Agreement) for the Target Program pursuant to the Master Agreement or (iii) any member of such Party's senior management.

1.99 "**Late Stage Development Supply Requirements**" means the quantities of Collaboration Products (and placebo) that are reasonably required by Licensee to perform its Development activities with respect to Collaboration Product after Phase 2 Completion, including Phase 3 Clinical Trial and post-Regulatory Approval Development activities.

1.100 "**Late Stage Supply Requirements**" means the Late Stage Development Supply Requirements and Commercial Supply Requirements.

1.101 "**Legal Dispute**" means any dispute related to a Party's alleged material breach of this Agreement or the validity, breach, termination or interpretation of this Agreement, or intellectual property-related disputes.

1.102 "**License Agreement**" means (i) any License Agreement (as defined in the Master Agreement) that is entered into by the Parties (or their respective Affiliates) pursuant to the Master Agreement and [***].

1.103 "**Licensee**" means [_____][17].

1.104 "**Licensee Background Technology**" means (a) Information that is necessary or reasonably useful to Exploit any Collaboration Product and (b) Patent Rights that Cover any Collaboration Product or the Exploitation of any Collaboration Product, in each case, ((a) and (b)), that are Controlled by Licensee or its Affiliates during the Term, but excluding Licensee Collaboration IP and Licensee's interest in the Joint Collaboration IP. [Notwithstanding the foregoing, Licensee Background Technology shall exclude (i) any Information related to any Unlicensed Component and (ii) any Patent Rights that Cover the composition or use or manufacture of any Unlicensed Component (alone or in combination).][18]

[17] Note to Draft: Fill in either "Regeneron" or "Alnylam" depending on which Party is Licensee (based on which Party is Licensee for this Agreement pursuant to the Master Agreement).

[18] Note to Draft: Delete this bracketed language if Alnylam is Licensee and replace with "Notwithstanding the foregoing, Licensee Background Technology shall exclude (i) any Information specifically related to any Unlicensed Component (to the extent not related to a Combination Product or any other combination of such Unlicensed Component with an siRNA Directed to the Target) and (ii) any Patent Rights that Cover the composition or use or manufacture of any Unlicensed Component alone (but not claiming the composition, use, or manufacture of a Combination Product or other combination of such Unlicensed Component with an siRNA Directed to the Target)."

1.105 "**Licensee Background Technology Improvements**" means any developments, enhancements, modifications or other improvements to, or progeny, mutants, fragments, or derivatives of, [(x)][19] the Licensee Background Technology [or (y) any Unlicensed Component Controlled by Licensee or any of its Affiliates,][20] that (a) are made by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement, and (b) with respect to any of the foregoing constituting (i) Information, are not specifically and solely related to any Product-Specific Factor and (ii) Patent Rights, do not include any claim the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.106 "**Licensee Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that is conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by individuals who are employees, agents or consultants of Licensee or its Affiliates or its or their Sublicensees, in each case, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a). Licensee Collaboration IP excludes Licensee's interest in Joint Collaboration IP and any Licensor Background Technology Improvements. Patent Rights constituting Licensee Collaboration IP are either Licensee Core Technology Patents or Licensee Product-Specific Patents, as the case may be.

1.107 "**Licensee Core Technology Know-How**" means Licensee Know-How other than Licensee Product-Specific Know-How.

1.108 "**Licensee Core Technology Patents**" means Licensee Patents other than Licensee Product-Specific Patents.

[19] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[20] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

1.109 "**Licensee In-License**" means any (a) Existing Licensee In-License, (b) Product-Specific In-License between Licensee (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent that such agreement is designated as a Licensee In-License pursuant to Section 6.5.1(a) or (c) Core Technology In-License between Licensee (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent such agreement is designated as a Licensee In-License pursuant to Section 6.5.1(b) or Section 6.5.1(c). In the event that a given Product-Specific In-License (as defined in the Master Agreement) or Core Technology In-License (as defined in the Master Agreement) between Licensee (or its Affiliates) and a Third Party was designated to be a [_____][21] In-License (as defined in the Master Agreement) for the Target Program pursuant to the Master Agreement, then such agreement shall also be a Licensee In-License for this Agreement (as a Product-Specific In-License or Core Technology In-License, as applicable, but shall not be an Existing Licensee In-License).

1.110 "**Licensee Indemnitees**" has the meaning set forth in Section 11.1.1.

1.111 "**Licensee Know-How**" means (a) the Information included in the Licensee Collaboration IP; (b) Licensee's interest in the Information included in the Joint Collaboration IP; and (c) the Information included in any Licensee Background Technology or in any Licensee Background Technology Improvements that is not in the public domain or otherwise generally known.

1.112 ["**Licensee Manufacturing Technology**" means Licensee Technology relating to the Manufacturing Process of a Collaboration Product that is Controlled by Licensee or its Affiliates during the Term.][22]

1.113 "**Licensee Patents**" means (a) the Patent Rights included in the Licensee Collaboration IP; (b) Licensee's interest in the Joint Collaboration Patents; and (c) the Patent Rights included in any Licensee Background Technology or in any Licensee Background Technology Improvements.

1.114 "**Licensee Product-Specific Know-How**" means Licensee Know-How that is specifically and solely related to Product-Specific Factors.

[21] Note to Draft: Fill in either "Regeneron" or "Alnylam" depending on which Party is Licensee (based on which Party is Licensee for this Agreement pursuant to the Master Agreement).
[22] Note to Draft: Delete this definition if Alnylam is Licensee.

1.115 "**Licensee Product-Specific Patents**" means the Licensee Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor, including those Patent Rights set forth on **Schedule 1.115**. [For clarity, Licensee Product-Specific Patents exclude Permitted Licensee Outside Product Patents.][23]

1.116 "**Licensee Technology**" means, collectively, Licensee Know-How and Licensee Patents.

1.117 "**Licensee Termination Core Technology Know-How**" means Licensee Termination Know-How other than Licensee Termination Product-Specific Know-How.

1.118 "**Licensee Termination Core Technology Patents**" means Licensee Termination Patents other than Licensee Termination Product-Specific Patents.

1.119 "**Licensee Termination Know-How**" means any Licensee Know-How existing as of the effective date of termination of this Agreement that (i) is not in the public domain or otherwise generally known and (ii) is necessary or reasonably useful to further Exploit a Terminated Product as such Terminated Product exists as of the effective date of termination of this Agreement.

1.120 "**Licensee Termination Patents**" means (a) any Licensee Patents existing as of the effective date of termination of this Agreement that are necessary or reasonably useful to Exploit a Terminated Product, as such Terminated Product exists as of the effective date of termination of this Agreement and (b) any Patent Rights that claim priority to any Licensee Patents in clause (a).

1.121 "**Licensee Termination Product-Specific Know-How**" means Licensee Termination Know-How that is specifically and solely related to Product-Specific Factors.

1.122 "**Licensee Termination Product-Specific Patents**" means the Licensee Termination Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.123 "**Licensor**" means [_____][24].

[23] Note to Draft: Delete bracketed language if Regeneron is Licensee.

[24] Note to Draft: Fill in either "Regeneron" or "Alnylam" depending on which Party is Licensor (based on which Party is the non-Licensee for this Agreement pursuant to the Master Agreement).

1.124 "**Licensor Background Technology**" means (a) Information that is necessary or reasonably useful to Exploit any Collaboration Product and (b) Patent Rights that Cover any Collaboration Product or the Exploitation of any Collaboration Product, in each case, ((a) and (b)), that are Controlled by Licensor or its Affiliates during the Term, but excluding Licensor Collaboration IP and Licensor's interest in the Joint Collaboration IP. [Notwithstanding the foregoing, Licensor Background Technology shall exclude (i) any Information related to any Unlicensed Component and (ii) any Patent Rights that Cover the composition or use or manufacture of any Unlicensed Component (alone or in combination).][25]

1.125 "**Licensor Background Technology Improvements**" means any developments, enhancements, modifications or other improvements to, or progeny, mutants, fragments, or derivatives of, [(x)][26] the Licensor Background Technology [or (y) any Unlicensed Component Controlled by Licensor or any of its Affiliates,][27] that (a) are made by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement, and (b) with respect to any of the foregoing constituting (i) Information, are not specifically and solely related to any Product-Specific Factor and (ii) Patent Rights, do not include any claim the practice of which necessarily requires the presence or direct use of a Product-Specific Factor.

1.126 "**Licensor Collaboration IP**" means (a) any improvement, discovery or Information, patentable or otherwise, that is conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by individuals who are employees, agents or consultants of Licensor or its Affiliates or its or their Sublicensees, in each case, under or in connection with this Agreement, and (b) any Patent Rights that Cover such improvements, discoveries or Information described in clause (a). Licensor Collaboration IP excludes Licensor's interest in Joint Collaboration IP and any Licensee Background Technology Improvements. Patent Rights constituting Licensor Collaboration IP are either Licensor Core Technology Patents or Licensor Product-Specific Patents, as the case may be.

[25] Note to Draft: Delete this bracketed language if Alnylam is Licensor and replace with "Notwithstanding the foregoing, Licensor Background Technology shall exclude (i) any Information specifically related to any Unlicensed Component (to the extent not related to a Combination Product or any other combination of such Unlicensed Component with an siRNA Directed to the Target) and (ii) any Patent Rights that Cover the composition or use or manufacture of any Unlicensed Component alone (but not claiming the composition, use, or manufacture of a Combination Product or other combination of such Unlicensed Component with an siRNA Directed to the Target)."

[26] Note to Draft: Delete this bracketed language if Alnylam is Licensor.

[27] Note to Draft: Delete this bracketed language if Alnylam is Licensor.

1.127 "**Licensor Core Technology Know-How**" means Licensor Know-How other than Licensor Product-Specific Know-How.

1.128 "**Licensor Core Technology Patents**" means Licensor Patents (other than Licensor Product-Specific Patents)[, including those Patent Rights set forth on **Schedule 1.128**].[28]

1.129 "**Licensor In-License**" means any (a) Existing Licensor In-License; or (b) Core Technology In-License between Licensor (or its Affiliates) and a Third Party entered into after the Effective Date but only to the extent such agreement is designated as a Licensor In-License pursuant to Section 6.5.1(c). In the event that a given Product-Specific In-License (as defined in the Master Agreement) or Core Technology In-License (as defined in the Master Agreement) between Licensor (or its Affiliates) and a Third Party was designated to be a [_____][29] In-License (as defined in the Master Agreement) for the Target Program pursuant to the Master Agreement, then such agreement shall also be a Licensor-In License for this Agreement (as a Product-Specific In-License or Core Technology In-License, as applicable, but shall not be an Existing Licensor In-License).

1.130 "**Licensor Indemnitees**" has the meaning set forth in Section 11.1.2.

1.131 "**Licensor Know-How**" means (a) the Information included in the Licensor Collaboration IP; (b) Licensor's interest in the Information included in the Joint Collaboration IP; and (c) the Information included in Licensor Background Technology or in any Licensor Background Technology Improvements that is not in the public domain or otherwise generally known.

1.132 "**Licensor Managed Patents**" has the meaning set forth in Section 10.2.

1.133 "**Licensor Patents**" means (a) the Patent Rights included in the Licensor Collaboration IP, (b) Licensor's interest in the Joint Collaboration Patents and (c) the Patent Rights included in any Licensor Background Technology or in any Licensor Background Technology Improvements.

[28] Note to Draft: Delete this bracketed language if Regeneron is Licensor.

[29] Note to Draft: Fill in either "Regeneron" or "Alnylam" depending on which Party is Licensor (based on which Party is the non-Licensee for this Agreement pursuant to the Master Agreement).

1.134 "**Licensor Product-Specific Know-How**" means Licensor Know-How that is specifically and solely related to Product-Specific Factors.

1.135 "**Licensor Product-Specific Patents**" means the Licensor Patents that include at least one claim, the practice of which necessarily requires the presence or direct use of a Product-Specific Factor, including those Patent Rights set forth on **Schedule 1.135**. [For clarity, Licensor Product-Specific Patents exclude Permitted Licensor Outside Product Patents.][30]

1.136 "**Licensor Technology**" means, collectively, Licensor Know-How and Licensor Patents.

1.137 "**MAA**" has the meaning set forth in the definition of "Drug Approval Application."

1.138 "**Major Market Country**" means each of the United States, Japan, France, Germany, Italy, the United Kingdom and Spain.

1.139 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, assembling, shipping, and holding of any Collaboration Product, or any intermediate thereof, and any placebo, as the case may be (including any devices or other delivery technologies that are packaged or distributed with a Collaboration Product), including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control, and management of any Third Party contractors conducting such activities.

1.140 "**Manufacturing Cost**" has the meaning set forth on **Schedule 1.140**.

1.141 "**Manufacturing Process**" means the then-current process for the Manufacture of Collaboration Products.

[30] Note to Draft: Delete bracketed language if Regeneron is Licensor.

1.142 [“**Manufacturing Technology Transfer**” has the meaning set forth in Section 5.2.2(c).][31]

1.143 [“**Manufacturing Technology Transfer Costs**” means the FTE Costs and Expenses and Out-of-Pocket Costs incurred by either Party in connection with a Manufacturing Technology Transfer pursuant to Section 5.2.1(b), Section 5.2.2(c) or Section 5.2.2(d). Manufacturing Technology Transfer Costs do not include the costs with respect to any Manufacturing Technology Transfer requested by Licensee due to a Material Supply Failure (which costs, for clarity, will be borne by Licensor), unless such Material Supply Failure is caused by or results, in whole or part, from an event of force majeure (as described in Section 13.1 of this Agreement) that applies to Licensor, its Affiliate or its Third Party contract manufacturer(s), in which case, such costs are Manufacturing Technology Transfer Costs.][32]

1.144 [“**Material Supply Failure**” means, [***] failure to deliver [***] at least [***] of the quantity of Collaboration Product in accordance with the specifications as ordered in a [***] period in accordance with the forecasting and ordering procedures in the Supply Agreement [***]. The Parties acknowledge that as of the Effective Date no Manufacturing Process has been developed, and no [***] has been selected, for the Manufacture of Collaboration Product at scale. Therefore, the Parties may discuss in good faith reasonable modifications to the quantitative standard for Material Supply Failure in this definition for inclusion in the Supply Agreement, based on forecast, lead time, Licensee’s supply requirements, [***] manufacturing slot availability, batch/order size and other relevant considerations known.] [***]

1.145 “**Materials**” means all tangible compositions of matter, devices, articles of manufacture, assays, animal models, biological, chemical, or physical materials, and other similar materials, including cell lines and animal models; provided that “Materials” excludes Collaboration Products.

1.146 “**MicroRNA**” or “**miRNA**” means a structurally defined functional RNA molecule usually between nineteen (19) and twenty-five (25) nucleotides in length, which is derived from an endogenous, genetically-encoded non-coding RNA which is predicted to be processed into a hairpin RNA structure that is a substrate for the double-stranded RNA-specific ribonuclease drosha and subsequently is predicted to serve as a substrate for the enzyme dicer, a member of the RNase III enzyme family.

[31] Note to Draft: Delete this definition if Alnylam is Licensee.

[32] Note to Draft: Delete this definition if Alnylam is Licensee.

1.147 "**MicroRNA Mimic**" means a single-stranded or double-stranded oligonucleotide with the same or substantially similar base composition and sequence (including chemically modified bases) as a particular natural miRNA and which is designed to mimic the activity of such miRNA. For clarity, MicroRNA Mimic excludes a double-stranded oligonucleotide which functions or is designed to function as an siRNA.

1.148 "**Milestone Payment**" means a Non-Rare Disease Milestone Payment or Rare Disease Milestone Payment, as applicable.

1.149 "**NDA**" has the meaning set forth in the definition of "Drug Approval Application."

1.150 "**Net Sales**" means, [***]

1.151 "**New Collaboration Product**" means a Collaboration Product (i) that has a different composition of matter from any other Collaboration Products for which the applicable Milestone Payment pursuant to Section 7.2.1 or 7.2.2, as applicable has been paid, and (ii) (A) with respect to any Development Milestone Event pursuant to Section 7.2.1, for which a new IND (and excluding, for clarity, a supplement or amendment to an existing IND) would be required to be submitted to the FDA in order to conduct the applicable Clinical Trial triggering a Milestone Payment pursuant to Section 7.2.1, or (B) with respect to any Commercial Milestone Event pursuant to Section 7.2.1 or 7.2.2, as applicable, for which a new NDA (and excluding, for clarity, a supplement or amendment to an existing NDA) would be required to be submitted to the FDA in order to market the applicable Collaboration Product in the United States.

1.152 "**New External Program**" has the meaning set forth in Section 3.1.9.

1.153 "**New Program Permitted Dual Sequence Uses**" has the meaning set forth in Section 3.1.9.

1.154 "**Non-Acquiring Party**" has the meaning set forth in Section 6.7.2(a).

1.155 "**Non-Approval Trials**" means any surveys, registries and Clinical Trials not intended to gain Regulatory Approval or any additional labeled indications, excluding any open label extension studies of the Collaboration Products.

1.156 "**Non-Breaching Party**" has the meaning set forth in Section 12.2.

1.157 "**Non-Relevant Organ Delivery Technology**" means [***].

1.158 [“**Ongoing Candidate Discovery Development Activities**” has the meaning set forth in the definition of “Alnylam Specific Activities.”][33]

1.159 “**Out-of-Pocket Costs**” means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the paying Party’s Accounting Standards) by either Party or its Affiliates in connection with activities under this Agreement, excluding FTE Costs and Expenses.

1.160 “**Party**” and “**Parties**” has the meaning set forth in the preamble hereto.

1.161 “**Patent Rights**” means (a) all issued patents (including any extensions, restorations by any existing or future extension or registration mechanism (including patent term adjustments, patent term extensions, supplemental protection certificates or the equivalent thereof), substitutions, confirmations, re-registrations, re-examinations, and patents of addition); (b) patent applications (including all provisional applications, substitutions, requests for continuation, continuations, continuations-in-part, divisionals and renewals); (c) inventor’s certificates; and (d) all equivalents of the foregoing in any country of the world.

1.162 [“**Permitted Claim Scope**” means [***]

1.163 “**Permitted Competing Product**” means any [(a)] Competing Products Directed to the Target pursuant to the exception to exclusivity set forth in Section 6.7.1(a)(A)[, and (b) Competing Products set forth on **Schedule 1.163**.][34]

1.164 “**Permitted Dual Sequence**” means [***].

1.165 “**Permitted Dual Sequence Uses**” means, with respect to any Permitted Dual Sequence, [***], as applicable.

1.166 “**Permitted Licensee Outside Product**” means [***].

[33] Note to Draft: Delete this definition if Alnylam is Licensee.

[34] Note to Draft: Include this schedule only if the Target was a CNS Target or Eye Target under the Master Agreement and there were Competing Products Directed to the Target that were permitted with respect to the Target pursuant to subsection (C) or (D) of Section 5.7.1(a) of the Master Agreement. If included, the schedule should include the applicable exceptions.

1.167 [“**Permitted Licensee Outside Product Patents**” means (a) any Patent Rights classified as “Permitted Licensee Outside Product Patents” in accordance with Section 8.2.1(a)(iii)(B) and (b) any Patent Rights issuing therefrom.][35]

1.168 “**Permitted Licensor Outside Product**” means [***].

1.169 [“**Permitted Licensor Outside Product Patents**” means (a) any Patent Rights classified as “Permitted Licensor Outside Product Patents” in accordance with Section 8.2.1(a)(ii)(A)(a) and (b) any Patent Rights issuing therefrom.][36]

1.170 “**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.171 “**Phase 1 Clinical Trial**” means a human clinical trial of a Collaboration Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, or a similar clinical study prescribed by the applicable Regulatory Authorities, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(a), as amended.

1.172 “**Phase 2 Clinical Trial**” means a human clinical trial of a Collaboration Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, or a similar clinical study prescribed by the applicable Regulatory Authorities, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(b), as amended.

1.173 “**Phase 2 Completion**” means the completion of the Phase 2 Clinical Trials that were commenced prior to the Initiation of the first Registration Enabling Trial hereunder for the first Collaboration Product.

[35] Note to Draft: Remove definition if Regeneron is the Licensee or if the Target is not a Designated Target.
[36] Note to Draft: Remove definition if Alnylam is the Licensee or if the Target is not a Designated Target.

1.174 "**Phase 3 Clinical Trial**" means a human clinical trial of a Collaboration Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use and to determine warnings, precautions, and adverse reactions that are associated with such Collaboration Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Collaboration Product, including all tests and studies that are required by the FDA, pursuant to Applicable Law or otherwise.

1.175 "**Post-Termination Payments**" has the meaning set forth in **Schedule 12.6.2**.

1.176 "**Pre-Existing Affiliates**" has the meaning set forth in Section 6.7.2(e).

1.177 "**Pricing Approval**" means such approval, agreement, determination or governmental decision establishing prices for a Collaboration Product that can be charged to consumers and will be reimbursed by Regulatory Authorities in countries where Regulatory Authorities of such countries approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.178 "**Product Labeling**" means, with respect to a Collaboration Product in a country in the Territory, (a) the Regulatory Authority approved full prescribing information for such Collaboration Product for such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Collaboration Product in such country.

1.179 "**Product Regulatory Documentation**" has the meaning set forth in Section 9.1.

1.180 "**Product-Related In-License**" means a license or other similar agreement with a Third Party (other than the Existing Licensor In-Licenses and the Existing Licensee In-Licenses) to license or obtain any similar right or interest in any (a) Information necessary or reasonably useful to Exploit any Collaboration Product or (b) Patent Right that Covers any Collaboration Product or the Exploitation thereof.

1.181 "**Product-Related IP**" has the meaning set forth in Section 8.3.2.

1.182 "**Product-Related Patents**" has the meaning set forth in Section 8.2.1(a).

1.183 "**Product-Specific Factors**" means [***].

1.184 "**Product-Specific Information**" has the meaning set forth in Section 9.1.

1.185 "**Product-Specific In-License**" means a Product-Related In-License for Information that is primarily related to, or Patent Rights that primarily claim, Product-Specific Factors.

1.186 "**Product Trademarks and Domain Names**" means the Trademark(s) and any domain names to be used by Licensee or its Affiliates or Sublicensees for the Commercialization of Collaboration Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

1.187 "**Promotional Materials**" means, with respect to each Collaboration Product and country in which such Collaboration Product is or will be sold, promotional, advertising, communication and educational materials relating to such Collaboration Product for use in connection with the marketing, promotion and sale of such Collaboration Product in such country, and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.188 ["**Proof of Principle Criteria**" means the criteria to be mutually agreed to by the Parties prior to the commencement of the first Phase 1 Clinical Trial for the Relevant Organ Product, as described in more detail in the Master Agreement.

1.189 "**Proof of Principle Study**" means a Clinical Trial conducted under this Agreement that is designed to meet the Proof of Principle Criteria and identified by the Licensee to the JSC pursuant to Section 3.1.6 hereof.][37]

1.190 "**Proposal**" has the meaning set forth in **Schedule 1**.

1.191 "**Proprietary Unlicensed Component**" means, with respect to a given Party, an Unlicensed Component that is (a) proprietary to such Party (or its Affiliate) or (b) otherwise controlled (through license or otherwise) by such Party (or its Affiliate).

1.192 ["**Quality Agreement**" has the meaning set forth in Section 5.2.1(b).][38]

1.193 "**Rare Disease**" means a disease indication to be treated by a given Collaboration Product where the target population in the United States [***] patients. Any dispute regarding whether a given disease indication is a Rare Disease shall be an Expedited Matter.

[37] Note to Draft: Definitions of Proof of Principle Criteria and Proof of Principle Study will be included only if the Target is an Eye Target or CNS Target.
[38] Note to Draft: Delete this definition if Alnylam is Licensee.

1.194 "**Regeneron**" has the meaning set forth in the preamble hereto.

1.195 "**Regeneron Mice**" means Regeneron's proprietary, genetically engineered mice, and any progeny of such mice (including cross-bred progeny resulting from producing a genetically engineered mouse by breeding or by using any portion of any of Regeneron's proprietary genetically engineered mice) or other mice derived therefrom.

1.196 "**Registration Enabling Trial**" means a human clinical trial (whether or not designated a Phase 3 Clinical Trial) of a Collaboration Product (a) the results of which, together with prior data and information concerning such Collaboration Product, are intended at the time such human clinical trial is Initiated to establish that such Collaboration Product is safe and effective for its intended use; and (b) that forms the basis (alone or with one or more additional Registration Enabling Trials) of an effectiveness claim in support of a Regulatory Approval for such Collaboration Product, in each case ((a) and (b)), as acknowledged in writing by the FDA for any human clinical trial that does not meet the criteria for a Phase 3 Clinical Trial at the time such human clinical trial is Initiated.

1.197 "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, or market a Collaboration Product in such country, including, where applicable, (a) Pricing Approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) labeling approval.

1.198 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Collaboration Product in the Territory.

1.199 "**Regulatory Documentation**" means all (a) applications (including all INDs and Drug Approval Applications and other major regulatory filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files.

1.200 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Collaboration Product other than Patent Rights.

1.201 "**Relevant Organ**" means [_____][39].

1.202 "**Relevant Organ Product**" means any product containing siRNA that has been specifically engineered or selected to be Directed to the Target as expressed in the Relevant Organ; provided that such product shall still be a "Relevant Organ Product" even if such product is also Directed to such Target as expressed in another organ(s) in the body.

1.203 "**Royalties**" has the meaning set forth in Section 7.1.1.

1.204 "**Royalty Term**" means, with respect to a Collaboration Product and a country, the period commencing on the date of the First Commercial Sale of such Collaboration Product in such country and continuing until the latest of (a) the expiration of the last Valid Claim in such country of a (i) Licensor Patent (other than any Licensor Core Technology Patent that is excluded for purposes of the Royalty Term pursuant to Section 8.3.3), (ii) Joint Collaboration Patent, (iii) Licensee Product-Specific Patent or (iv) Patent Right within the [_____][40] Collaboration IP (as defined in the Master Agreement) that has been filed and is Controlled by Licensee (or its Affiliate) as of the Effective Date (including any other Licensee Patent that claims priority to any such Patent Right in this clause (iv)), in each case that Covers such Collaboration Product, provided that the use or sale of such Collaboration Product by Licensee (or its Affiliate or Sublicensee) in such country infringes such Valid Claim in such country (notwithstanding any license or ownership interest therein), (b) expiration of Regulatory Exclusivity for the such Collaboration Product in such country and (c) the [***] anniversary of the First Commercial Sale of such Collaboration Product in such country.

1.205 "**Rules**" has the meaning set forth in **Schedule 1**.

1.206 ["**Shared Facility**" has the meaning set forth in **Schedule 1.140**.][41]

1.207 "**siRNA**" means an oligonucleotide composition of native or chemically modified RNA that targets a gene through activation of the RNA interference pathway, and that is not a MicroRNA, MicroRNA antagonist or MicroRNA Mimic.

[39] Note to Draft: Insert the definition of "Liver", "Eye" or "CNS" from the Master Agreement, as applicable. In the event that any other organs are to be included in this Agreement pursuant to Section 5.7.1(a)(C)(b) of the Master Agreement, then this Agreement will need to be amended to include such other organs, as applicable, as set forth in Section 5.7.1(a)(C)(b) of the Master Agreement.

[40] Note to Draft: Insert "Regeneron" if Regeneron is Licensee, or insert "Alnylam" if Alnylam is Licensee.

[41] Note to Draft: Delete this definition if Alnylam is Licensee.

1.208 "**Sublicensed Party**" has the meaning set forth in Section 6.5.4.

1.209 "**Sublicensee**" means a Third Party that is granted, in accordance with this Agreement, a (sub)license by a Party or its Affiliates to intellectual property licensed under this Agreement by such Party or its Affiliates to, or to such Party and its Affiliates by, the other Party or its Affiliates, to Develop or Commercialize a Collaboration Product.

1.210 "**Sublicensor Party**" has the meaning set forth in Section 6.5.4.

1.211 ["**Supply Agreement**" has the meaning set forth in Section 5.2.1(b).][42]

1.212 ["**Supply Price**" has the meaning set forth in Section 5.2.1(b).][43]

1.213 "**Target**" means the target identified on **Schedule 1.213**.[44]

1.214 "**Target Program**" has the meaning set forth in the recitals.

1.215 "**Term**" has the meaning set forth in Section 12.1.

1.216 "**Terminated Product**" means any Collaboration Product that is the subject of Development or Commercialization by or on behalf of Licensee in the Territory as of the effective date of termination of this Agreement, but excluding [***].

1.217 "**Termination Transition Agreement**" has the meaning set forth in **Schedule 12.6.2**.

1.218 "**Territory**" means the entire world.

[42] Note to Draft: Delete this definition if Alnylam is Licensee.
[43] Note to Draft: Delete this definition if Alnylam is Licensee.
[44] Note to Draft: Add the identity of the Target under this Agreement on **Schedule 1.213** at the time of execution of this Agreement.

1.219 "**Third Party**" means any Person other than Licensor, Licensee and their respective Affiliates.

1.220 "**Third Party Acquisition**" has the meaning set forth in Section 6.7.2(a).

1.221 "**Third Party Infringement Action**" has the meaning set forth in Section 8.6.1.

1.222 "**Third Party Provider**" has the meaning set forth in Section 3.1.5.

1.223 "**Third Party Transaction**" means any transaction pursuant to which Licensee or its Affiliates grants a license, sells or otherwise grants or transfers, including by option, to any Third Party (other than in connection with (i) a Change of Control (provided, however that any such transaction shall be considered a "Third Party Transaction" where, as of the consummation of such transaction, the Collaboration Product(s) which are the subject matter of this Agreement constitutes a majority of the assets of Licensee) or (ii) a subcontract as permitted pursuant to Section 3.1.4) rights in or to, including any rights to further Develop or Commercialize, one or more Collaboration Products.

1.224 "**Third Party Transaction Proceeds**" means, with respect to a Third Party Transaction, any and all proceeds received by Licensee or any of its Affiliates from Third Parties in respect of such Third Party Transaction, including (a) upfront and milestone payments; (b) royalties, sales milestones, profit share and other payments based on the sales of a Collaboration Product; (c) the fair market value of any equity or debt securities issued in respect of such Third Party Transaction to such Party or its Affiliates that exceeds any amount paid by such Party or its Affiliates for such securities; (d) the amount by which any amount paid by a Third Party to such Party or its Affiliates for any equity or debt securities issued to such Third Party in respect of such Third Party Transaction exceeds the fair market value of such securities; (e) the amount by which the transfer price for any Collaboration Product paid by a Third Party to such Party or its Affiliates exceeds the actual Manufacturing Costs for such Collaboration Product; (f) the fair market value of any other form of consideration paid to, or received by or otherwise recognized by such Party or its Affiliates by or from a Third Party in connection with such Third Party Transaction as reasonably agreed by the Parties; but excluding any amounts received by Licensee or any of its Affiliates as (i) reimbursement for research and development costs that were actually incurred by a Party for the Development of the Collaboration Product(s) that are the subject of the Third Party Transaction, or (ii) bona fide pre-payment of research and development costs incurred by Licensee, for the Development of the Collaboration Product(s) that are the subject of the Third Party Transaction. If a Third Party Transaction includes products or intellectual property other than Collaboration Products or intellectual property claiming or Covering Collaboration Products, the Parties shall mutually agree upon a fair and reasonable allocation of the Third Party Transaction

Proceeds. Any dispute regarding (x) the fair market value of any equity or debt securities issued in respect of a Third Party Transaction, (y) the fair market value of any other form of consideration paid to, or received by or otherwise recognized by a Party or its Affiliates by or from a Third Party in connection with a Third Party Transaction or (z) the allocation of Third Party Transaction Proceeds between the Collaboration Products and other products or intellectual property included in the applicable Third Party Transaction, in each case ((x) through (z)), shall be a Financial Dispute.

1.225 "**Third Party Transaction Proceeds Percentage**" means [***].

1.226 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.227 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.228 "**Unlicensed Component**" means (a) any API of a Combination Product that is not an siRNA Directed to the Target or (b) any API that is otherwise administered in a Clinical Trial of a Collaboration Product (in accordance with the protocol for such Clinical Trial) that is not an siRNA Directed to the Target.

1.229 "**Valid Claim**" means a claim of (a) any issued and unexpired Patent Right whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a patent application prosecuted in good faith that has been pending less than [***] years from the date of filing of the earliest patent application to which such patent application claims priority, which claim has not been cancelled, withdrawn or abandoned, or finally rejected by an administrative agency action from which no appeal can be taken.

Article 2
JOINT STEERING COMMITTEE AND ALLIANCE MANAGERS

2.1 Joint Steering Committee.

2.1.1 Formation. Within fifteen (15) days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"). The JSC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to have discussions with respect to the Exploitation of the

Collaboration Products; provided that the Parties may agree to increase or decrease the number of equal representatives from each Party. From time to time, each Party may replace one or more of its representatives to the JSC on written notice to the other Party. Each Party shall appoint one of its representatives to serve as a co-chairperson of the JSC, and a Party may change its appointed co-chairperson from time to time upon written notice to the other Party.

2.1.2 Specific Responsibilities. The JSC shall discuss the Development, Commercialization, Manufacture and other Exploitation of the Collaboration Products in the Territory pursuant to this Agreement. For clarity, the JSC shall be a forum for discussion only and shall not have any decision-making authority.

2.1.3 Meetings. The Joint Steering Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once each Calendar Quarter during the Term (provided that following the First Commercial Sale of the first Collaboration Product, the Joint Steering Committee shall hold meetings no less frequently than once every other Calendar Quarter), commencing from and after the time the Joint Steering Committee is established as provided herein unless the co-chairpersons agree otherwise. All Joint Steering Committee meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons; provided, that, prior to the First Commercial Sale of the first Collaboration Product, the Joint Steering Committee shall meet in person at least once each Calendar Year, unless otherwise agreed by the Parties. Unless otherwise agreed by the Parties, all in-person meetings of the Joint Steering Committee shall be held on an alternating basis between Licensee's facilities and Licensor's facilities. A reasonable number of other representatives of a Party may attend any Joint Steering Committee meeting as non-voting observers (provided, that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in ARTICLE 9). Each Party shall be responsible for all of its own expenses of participating in the Joint Steering Committee. Either Party's representatives on a Joint Steering Committee may call a special meeting of the Joint Steering Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.

2.1.4 Procedural Rules. The Joint Steering Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Joint Steering Committee shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party.

2.1.5 Committees under the Master Agreement and other License Agreements and Co-Co Collaboration Agreements. If agreed to by the Parties, the JSC hereunder can be the same as the equivalent committee under the Master Agreement or any other License Agreement or

Co-Co Collaboration Agreement (e.g., the JSC hereunder can be the same committee as the JSC under the Master Agreement or any other License Agreement or Co-Co Collaboration Agreement).

2.2 Alliance Manager. Each Party shall appoint a senior representative who possesses a general understanding of this Agreement and pharmaceutical research, clinical, regulatory, manufacturing and commercialization matters and who shall oversee contact between the Parties for all matters with respect to this Agreement and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

Article 3
DEVELOPMENT AND REGULATORY

3.1 Development Activities.

3.1.1 Transition of Development Activities from Master Agreement. To the extent that Licensor was performing Development activities with respect to the Target Program under the Master Agreement, Licensor shall use Commercially Reasonable Efforts to provide cooperation and assistance to Licensee, as reasonably requested by Licensee, to enable Licensee to assume the continuation of such Development of the Collaboration Products in the Territory pursuant to this Agreement[; provided, however, that Licensor shall not transition to Licensee any Alnylam Specific Activities][45]. Such cooperation and assistance shall be provided in a prompt and timely manner.

3.1.2 Development by Licensee. Licensee (itself or through its Affiliates or Sublicensees) shall have the sole right to Develop Collaboration Products in the Territory, and shall be responsible for all of its costs and expenses in connection with the Development of the Collaboration Products. [Licensee shall, in good faith, include the Development of Collaboration Product as a Relevant Organ Product in its initial development plan, to the extent such Development remains reasonable in light of all circumstances then existing.][46]

3.1.3 Diligence. Licensee shall use Commercially Reasonable Efforts to Develop a Collaboration Product [***].

3.1.4 [**Alnylam Specific Activities**. [***]

[45] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

[46] Note to Draft: Delete this bracketed language if Alnylam is Licensee or if the Target is not an Eye Target.

3.1.5 Subcontracting. Each Party shall have the right to subcontract any of its Development activities under this Agreement to a Third Party (a "**Third Party Provider**") without the other Party's consent [(provided that Licensor shall not subcontract any activities within the Alnylam Specific Activities without Licensee's prior consent, such consent not to be unreasonably withheld, conditioned or delayed, except that Licensor may subcontract those activities set forth on **Schedule 3.1.5** to those Third Party Providers as set forth on such schedule to the extent Licensor subcontracts such activities in the ordinary course of Licensor's business, which schedule may be updated from time to time by the Parties to include additional Third Party Providers upon Licensor's reasonable request and Licensee's consent, not to be unreasonably withheld, conditioned or delayed)][47]; provided that any subcontract entered into by a Party pursuant to this Section 3.1.5 must (a) be in writing, (b) be consistent with the terms and conditions of this Agreement, including containing confidentiality provisions at least as protective as those contained in ARTICLE 9, and (c) provide the other Party with the same rights with respect to any intellectual property arising from the subcontracted activities as it would have if the subcontracting Party performed such activities under this Agreement (except that with respect to any subcontract entered into with a Third Party contract manufacturer, such Third Party may retain ownership of any general manufacturing process improvement of general application; provided that such Third Party grants the subcontracting Party a sublicenseable license with respect to any such improvement to the extent related to a Collaboration Product). In the event the subcontracting Party seeks to subcontract with an academic, governmental, not-for-profit or public institution and is unable to comply with subsection (c) above because the institution has standard policies against such intellectual property obligations, then the subcontracting Party may submit a written request to the other Party for its consent to such subcontract through the Alliance Managers. If the other Party fails to respond to such request within [***] weeks after receipt of such written request, such request shall be deemed to have been approved, and the subcontracting Party may proceed with the subcontract. In any event, the subcontracting Party shall (x) oversee the performance by its subcontractors of the activities subcontracted pursuant to this Section 3.1.4 in a manner that would be reasonably expected to result in their timely and successful completion and (y) be responsible and liable for the actions and omissions of its subcontractors. No subcontracting pursuant to this Section 3.1.4 shall relieve the subcontracting Party of any of its obligations, or the other Party of any of its rights, under this Agreement.

[47] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

3.1.6 [**Proof of Principle Study**. Promptly following mutual agreement on the Proof of Principle Criteria by the Parties, in accordance with and more particularly described in the Master Agreement, Licensee shall identify such Proof of Principle Criteria in writing to the JSC. [***]

3.1.7 Compliance. Each Party shall perform or cause to be performed any and all of its Development activities in a good scientific manner and in compliance with all Applicable Law.

3.1.8 siRNAs from Other License Agreements or Co-Co Collaboration Agreements. [***]

3.1.9 [**Additional Permitted Dual Sequences**. [***]

3.2 Information Exchange. As long as Licensee is conducting Development activities under this Agreement, upon the reasonable request of Licensee, Licensor shall provide to Licensee Information that is licensed to Licensee under this Agreement to the extent that it is necessary or reasonably useful for Licensee for Developing any Collaboration Product or for filing, obtaining or maintaining INDs or Regulatory Approval for any Collaboration Product, including copies of all material scientific information and data related to such Collaboration Product.

3.3 Records and Reports.

3.3.1 [Each of Licensor and][48] Licensee shall, and shall ensure that its Third Party Providers, maintain complete, current and accurate records of all of its Development activities under this Agreement and all data and other information resulting from such Development activities, which records shall (a) be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, (b) properly reflect all work done and results achieved in the performance of such Development activities, and (c) record only such Development activities and shall not include or be commingled with records of activities that are not conducted under this Agreement. Licensee [or Licensor, as the case may be,][49] shall retain, or cause to the retained, such records for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law.

[48] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[49] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

3.3.2 Within thirty (30) days following the end of each Calendar Year during which Licensee is conducting Development activities, Licensee shall provide the Joint Steering Committee a summary of material Development activities that were conducted over the preceding Calendar Year or that Licensee plans to conduct in the current or next Calendar Year (including to the extent available the design of any clinical trial that they intend to initiate or conduct during such period) and shall promptly notify the Joint Steering Committee of material developments in the Development and Regulatory Approval of the Collaboration Products in the Major Market Countries. At Licensor's reasonable request from time to time, Licensee shall promptly provide Licensor with additional material information regarding completed, ongoing, or anticipated Development efforts.

3.3.3 Licensee shall provide Licensor with copies of or access to clinical safety data affecting each Collaboration Product or the class (e.g., serious adverse events, emerging safety issues) and other reasonable information to enable Licensor to conduct platform-wide safety signal analyses. If requested by a Party, the Parties shall reasonably agree on timelines to provide such data, and in particular with respect to clinical safety data, in order for the Parties to be able to comply with any regulatory reporting requirements.

3.3.4 Notwithstanding anything to the contrary contained herein (including Sections 3.4.1 and 5.1), neither Party shall be required to provide to, or otherwise share with, the other Party any data (including Development Data and CMC information) specific to such Party's Proprietary Unlicensed Component, unless otherwise required by a Regulatory Authority.

3.4 Regulatory Matters.

3.4.1 Regulatory Responsibilities.

(a) As between the Parties, Licensee shall have the sole right to prepare, obtain, and maintain INDs, Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions, and to conduct communications with the Regulatory Authorities, for Collaboration Products in the Territory (which shall include filings or communications with the Regulatory Authorities with respect to Development activities). [Licensor shall support Licensee, as reasonably requested by Licensee, in obtaining INDs and Regulatory Approvals for the Collaboration Products, and in the activities in support thereof, including providing documents or other materials necessary or reasonably useful to obtain any such INDs and Regulatory Approvals and consulting with respect thereto. [***]

(b) [***]

(c) All Regulatory Documentation (including all Regulatory Approvals and Product Labeling) relating to the Collaboration Products shall be owned by, and shall be the sole property and held in the name of, Licensee or its designated Affiliate, Sublicensee or designee.

3.4.2 Recall, Market Suspension or Market Withdrawal. Licensee shall make every reasonable effort to notify Licensor promptly (but in no event later than forty-eight (48) hours) following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Collaboration Product in the Territory, and shall include in such notice the reasoning behind such determination, and any supporting facts. Licensee shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Territory. If a recall, market suspension, or market withdrawal is mandated by a Regulatory Authority in the Territory, Licensee shall initiate such a recall, market suspension, or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 3.4.2, Licensee shall be solely responsible for the execution thereof, and Licensor shall reasonably cooperate in all such recall efforts. Without limiting ARTICLE 11, (a) if and to the extent that a recall, market suspension, or market withdrawal resulted from a Party's or any of its Affiliate's material breach of its obligations hereunder, or from such Party's or any of its Affiliate's gross negligence or willful misconduct, such Party shall be responsible for the costs and expenses of such recall, market suspension, or market withdrawal incurred by or on behalf of either Party, (b) except as set forth in the foregoing clause (a), Licensee shall be responsible for the costs and expenses of such recall, market suspension, or market withdrawal incurred by or on behalf of either Party.

3.5 Material Transfer. In the event a Party transfers to the other Party any Materials under this Agreement, the receiving Party shall: (a) use such Materials solely for the purpose of exercising its rights or fulfilling its obligations under this Agreement and for no other purpose; and (b) not transfer such Materials to any Third Party without the providing Party's prior written consent, provided that the receiving Party shall have the right to transfer such Materials to its Sublicensees or subcontractors solely to the extent for such Third Party to conduct the activities on behalf of, or as a Sublicensee of, such receiving Party in furtherance of this Agreement. In the event the Parties anticipate the transfer of any patient samples or patient information, the Parties shall negotiate in good faith and enter into an agreement governing such transfer and subsequent use, in compliance with all Applicable Law.

3.6 Delivery Technology. At any time during the Term, either Party may propose in writing to the other Party that a targeting ligand or other delivery technology is or is not a type of Non-Relevant Organ Delivery Technology, as measured by [***]. Within thirty (30) days of receiving such request, together with reasonable supporting data from the requesting Party, if any,

the non-requesting Party may agree or object. Upon any such objection, the proposing Party, if it so elects, may elect to invoke the dispute resolution process set forth in Section 13.5.2(c) to determine if a targeting ligand or other delivery technology is or is not a type of Non-Relevant Organ Delivery Technology. Upon any agreement by the Parties or resolution by the dispute resolution process set forth in Section 13.5.2(c), the JSC will record the applicable classification of the targeting ligand or other delivery technology in its minutes; provided that, for clarity, either Party shall have the right to subsequently dispute the determination made pursuant to this Section 3.6 if new information becomes available with respect to such targeting ligand or other delivery technology, and if a new determination is made, the JSC minutes will be updated to reflect such new determination (provided that, if (a) there was an initial determination made pursuant to this Section 3.6 that a particular targeting ligand or other delivery technology was Non-Relevant Organ Delivery Technology, and (b) it is subsequently determined that such targeting ligand or other delivery technology is not Non-Relevant Organ Delivery Technology, [***].

Article 4
COMMERCIALIZATION

4.1 In General. Licensee (itself or through its Affiliates or Sublicensees) shall have the sole right to Commercialize Collaboration Products in the Territory, and shall be responsible for all of its costs and expenses incurred in connection with the Commercialization of the Collaboration Products.

4.2 Diligence. Licensee shall use Commercially Reasonable Efforts to Commercialize a Collaboration Product [***] following receipt of Regulatory Approval therefor in the applicable country in the Territory.

4.3 Compliance with Applicable Law. Licensee shall, and shall cause its Affiliates to, comply with all Applicable Law with respect to the Commercialization of Collaboration Products.

4.4 Booking of Sales; Distribution. Licensee shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Collaboration Products in the Territory and to perform or cause to be performed all related services. Licensee shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Collaboration Products in the Territory.

4.5 Promotional Materials. Licensee will be responsible for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the world.

4.6 Product Trademarks and Domain Names. Subject to Section 4.7, Licensee shall have the right to determine and shall own the Product Trademarks and Domain Names to be used with respect to the Exploitation of the Collaboration Products on a worldwide basis. Neither Party shall, nor it permit its Affiliates to, (a) use in their respective businesses (except, with respect to Licensee, under this Agreement), any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks and Domain Names, or (b) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks and Domain Names.

4.7 Use of Corporate Names.

4.7.1 Licensee shall have no obligation to include Licensor's Corporate Names on materials related to the Collaboration Products (including Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Collaboration Products), except that to the extent Licensee is required under Applicable Law to include Licensor's Corporate Names on materials related to the Collaboration Product (including Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Collaboration Products) it shall do so.

4.7.2 During the Term, Licensee shall submit samples of each such Product Labeling, trade packaging, internet pages, social media, samples and Promotional Materials containing Licensor's Corporate Name to Licensor for its prior approval (which approval shall not be unreasonably withheld, conditioned or delayed) at least fifteen (15) days before the first dissemination of such materials. Failure of Licensor to object within such fifteen (15)-day period shall constitute approval of Licensee's Product Labeling, trade packaging, internet pages, social media, samples and all Promotional Materials.

4.8 Commercialization Reports. Approximately twenty-four (24) months prior to, and again approximately twelve (12) months prior to, the expected date of First Commercial Sale of a Collaboration Product, Licensee shall provide the Joint Steering Committee a written report (in electronic form) summarizing the Commercialization activities (if any) undertaken by or on behalf of Licensee with respect to each Collaboration Product in the Field during such Calendar Year. Commencing with the First Commercial Sale of a Collaboration Product in the Territory such reports shall be provided two (2) times per Calendar Year (for the first two Calendar Quarters and for the last two Calendar Quarters of each Calendar Year). The foregoing reports referred to in this Section 4.8 shall be in a level of detail that will provide Licensor with an update on the progress of the Commercialization activities. In addition, interim versions of such reports may be requested by Licensor with respect to the first Calendar Quarter and third Calendar Quarter of each Calendar

Year, it being understood that such interim reports may be less detailed than the regular reports covering two (2) Calendar Quarters.

Article 5
MANUFACTURING AND SUPPLY

5.1 Manufacturing Coordination. [***]

5.2 [50][**Manufacturing and Supply**.

5.2.1 Early Stage Supply Requirements.

(a) Licensor shall use Commercially Reasonable Efforts to adequately and timely Manufacture and supply the Early Stage Supply Requirements, which Manufacture and supply shall be in accordance with Applicable Law, including GMP, and this Agreement, as well as the Supply Agreement and the Quality Agreement once the Parties have executed the Supply Agreement and the Quality Agreement.

(b) The Parties shall negotiate in good faith and use diligent and good faith efforts to execute and deliver a definitive supply agreement for the supply of the Early Stage Supply Requirements (the "**Supply Agreement**") and related quality agreement (the "**Quality Agreement**") [***].

(c) [***].

5.2.2 Late Stage Supply Requirements.

(a) [***]

(b) [***]

(c) Technology Transfer to Licensee. [***]

(d) Additional Technology Transfers. [***]

5.2.3 Licensee's Contracts with Third Party Contract Manufacturers. [***]

5.2.4 Licensee's Efforts. [***]

5.2.5 Technology Transfer to Licensor. [***]

[50] Note to Draft: If Alnylam is Licensee, then the following Section 5.2 should be replaced with the alternative Section 5.2 below.

5.2.6 Costs of Manufacture. [***]

5.2.7 Certain Licensor Third Party Contractor Requirements. [***]

5.2 [ALTERNATIVE FOR SECTION 5.2] [**Manufacturing and Supply**.[51]

5.2.1 Licensee will, itself or through one or more of its Affiliates or through one or more Third Party contract manufacturers, Manufacture and supply the Early Stage Supply Requirements and the Late Stage Supply Requirements. Licensee shall use Commercially Reasonable Efforts to adequately and timely Manufacture and supply the Early Stage Supply Requirements and the Late Stage Supply Requirements, which Manufacture and supply shall be in accordance with Applicable Law, including GMP, and this Agreement.

5.2.2 [***]

5.2.3 [***]

5.2.4 [***]

Article 6
GRANT OF RIGHTS

6.1 Grants to Licensee. Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee:

6.1.1 subject to Section [6.4.3][52], an exclusive (including with regard to Licensor and its Affiliates), non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Licensor Product-Specific Patents and the Licensor Product-Specific Know-How, to Exploit the Collaboration Products in the Field in the Territory, which license shall be royalty-bearing pursuant to Section 7.1.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

[51] Note to Draft: If Alnylam is Licensee, then this alternative Section 5.2 replaces the Section 5.2 above.
[52] Note to Draft: Change this reference to Section 6.4.2 if Alnylam is Licensee.

6.1.2 a non-exclusive, non-transferable (except as permitted by Section 13.2), worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Licensor Core Technology Patents and the Licensor Core Technology Know-How, to Exploit the Collaboration Products in the Field in the Territory, which license shall be royalty-bearing pursuant to Section 7.1.1 during the Royalty Term with respect to each Collaboration Product in each country in the Territory, and after the expiration of the Royalty Term for a Collaboration Product in a country shall convert to a fully paid-up, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, for such Collaboration Product in such country;

6.1.3 subject to Section [6.4.3][53], an exclusive (including with regard to Licensor and its Affiliates), non-transferable (except as permitted by Section 13.2), fully paid-up, worldwide license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 6.3, under the Regulatory Approvals and any other Regulatory Documentation that Licensor or its Affiliates may Control that are related to a Collaboration Product as necessary for Exploiting such Collaboration Product in the Field in the Territory;

6.1.4 a non-exclusive license, with the right to grant sublicenses in accordance with Section 6.3, to use Licensor's Corporate Names solely as required to comply with, and in accordance with, Section 4.7, and for no other purpose; and

6.1.5 [a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, [***] to Exploit any product in the Territory that does not contain any siRNA, MicroRNA, MicroRNA antagonist or MicroRNA Mimic, or any single or double-stranded oligonucleotide designed to specifically hybridize to RNA and modulate the expression of the intended target.][54]

[53] Note to Draft: Change this reference to Section 6.4.2 if Alnylam is Licensee.

[54] Note to Draft: If Regeneron is Licensee, use this Section 6.1.5. If Alnylam is Licensee, delete this Section 6.1.5 and use the alternative Section 6.1.5 below.

6.1.5 [ALTERNATIVE SECTION 6.1.5] [a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, [***] to Exploit any product in the Territory containing siRNA (other than a Competing Product).][55]

Notwithstanding the foregoing in this Section 6.1, Licensee does not receive any rights under the license grants in this Section 6.1 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Licensor (or any of its Affiliates).

6.2 Grants to Licensor. Subject to the terms and conditions of this Agreement, Licensee hereby grants Licensor:

6.2.1 [a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, [***] to Exploit any product in the Territory containing siRNA (other than a Competing Product); and][56]

[ALTERNATIVE SECTION 6.2.1] [a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, perpetual, worldwide license (or sublicense), with the right to grant sublicenses through multiple tiers, [***] to Exploit any product in the Territory that does not contain any siRNA, MicroRNA, MicroRNA antagonist or MicroRNA Mimic, or any single or double-stranded oligonucleotide designed to specifically hybridize to RNA and modulate the expression of the intended target; and][57]

6.2.2 [a non-exclusive, non-transferable (except as permitted by Section 13.2), fully paid-up, worldwide license (or sublicense), with the right to grant sublicenses in accordance with Section 6.3, under the Licensee Technology, to Develop the Collaboration Products solely for purposes of performing the Alnylam Specific Activities as set forth in, and subject to, the development plan and budget agreed to pursuant to Section 3.1.4 and to Manufacture and supply the Early Stage Supply Requirements, and if applicable, the Late Stage Supply Requirements;][58]

[55] Note to Draft: If Alnylam is Licensee, use this alternative Section 6.1.5.

[56] Note to Draft; If Alnylam is Licensor, use this Section 6.2.1. If Regeneron is Licensor, delete this Section 6.2.1 and use the alternative Section 6.2.1 below.

[57] Note to Draft: If Regeneron is Licensor, then use this alternative Section 6.2.1.

[58] Note to Draft: Delete this Section 6.2.2 if Regeneron is Licensor.

Notwithstanding the foregoing in this Section 6.2, Licensor does not receive any rights under the license grants in this Section 6.2 to or for any Proprietary Unlicensed Component of a Combination Product Controlled by Licensee (or any of its Affiliates).

6.3 Sublicenses. [Either Party][59] shall have the right to grant sublicenses (or further rights of reference), through multiple tiers, under the licenses and rights of reference granted to Licensee in Section 6.1.1, Section 6.1.2, Section 6.1.3 or Section 6.1.4 [or to Licensor in Section 6.2.2][60], as applicable; provided that any such sublicenses to Develop or Commercialize a Collaboration Product shall be consistent with the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement. Licensee will promptly provide the other Party with a copy of any fully executed sublicense agreement with a Third Party covering any Commercialization sublicense granted hereunder. Each such sublicense agreement entered into by a Party shall contain a requirement that the Sublicensee comply with confidentiality and non-use provisions that are no less stringent than Section 9.1 with respect to the other Party's Confidential Information. Furthermore, the applicable Party shall use commercially reasonable efforts to ensure that, to the extent possible, each such sublicense agreement by it to a Sublicensee provides that any and all data and results, discoveries, inventions and other Information, whether patentable or not, arising out of the sublicense are owned by such Party or one of its Affiliates; provided that if, after using commercially reasonable efforts, the foregoing is not possible, then such Party shall ensure that it sufficiently Controls all such data and results, discoveries, inventions and other Information in order to grant the licenses to the other Party as contemplated under this Agreement. Notwithstanding any sublicense to a Sublicensee, the sublicensing Party shall remain responsible to the other Party for the performance of all of the sublicensing Party's obligations under, and compliance with, all applicable terms and conditions of, this Agreement, including any obligations delegated to its Sublicensees. For the avoidance of doubt, either Party may grant sublicenses, through multiple tiers, under the licenses granted to such Party under Section 6.1.5 or Section 6.2.1, as applicable, without the consent of the other Party and the foregoing provisions of this Section 6.3 shall not apply to such sublicenses.

[59] Note to Draft: Change this bracketed language to "Licensee" if Regeneron is Licensor.

[60] Note to Draft: Delete this bracketed language if Regeneron is Licensor.

6.4 No Implied License; Retention of Rights.

6.4.1 Except as expressly provided herein, nothing in this Agreement grants either Party or vests in either Party any right, title or interest in and to the Information, Patent Rights, Confidential Information, Trademarks or other intellectual property of the other Party (either expressly or by implication or estoppel), other than the license rights expressly granted hereunder and the assignments expressly made hereunder.

6.4.2 Notwithstanding anything to the contrary in this Agreement, and without limiting any rights granted or reserved to Regeneron pursuant to any other term or condition of this Agreement:

(a) Regeneron hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) all right, title and interest in and to the [_____][61] Technology to (i) perform its and their obligations under this Agreement; and (ii) subject to Section 6.7, develop, obtain and maintain regulatory approvals for, and to manufacture, commercialize, and otherwise exploit any compound or product, other than a Collaboration Product, in any field anywhere in the world; and

(b) Regeneron reserves the right to grant the licenses to Third Parties for the purposes described in Section 6.7.3.

6.4.3 Notwithstanding anything to the contrary in this Agreement, and without limiting any rights granted or reserved to Alnylam pursuant to any other term or condition of this Agreement, Alnylam hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) all right, title and interest in and to the [_____][62] Technology to (a) perform its and their obligations under this Agreement[, including (i) to perform the Alnylam Specific Activities, and (ii) to Manufacture and supply the Early Stage Supply Requirements and if applicable, the Late Stage Supply Requirements][63] and (b) subject to Section 6.7, develop, obtain and maintain regulatory approvals for, and to manufacture, commercialize, and otherwise exploit any compound or product, other than a Collaboration Product, in any field anywhere in the world.

[61] Note to Draft: If Regeneron is Licensor, then insert “Licensor”. If Regeneron is Licensee, then insert “Licensee”.
[62] Note to Draft: If Alnylam is Licensor, then insert “Licensor”. If Alnylam is Licensee, then insert “Licensee”.
[63] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

6.4.4 [***]

6.5 In-License Agreements.

6.5.1 Entry Into In-Licenses.

[***]

6.5.2 Additional Alnylam In-Licenses. In the event that a Patent Right licensed to Alnylam under an Additional Alnylam In-License actually is or will be infringed by Licensee's Development, Manufacture or Commercialization of a Collaboration Product in the Field and in the Territory in accordance with this Agreement, then such Additional Alnylam In-License will thereafter automatically be deemed to be an Existing [Licensor][64] In-License on a Collaboration Product-by-Collaboration Product basis, and all rights granted to [Licensor][65] thereunder will be deemed to be "Controlled" by [Licensor][66] and [sublicensed to Licensee under the applicable terms of Section 6.1][67], effective as of the later of (a) the date the applicable Patent Right issues and (b) the date that Licensee's Development, Manufacture or Commercialization of such Collaboration Product in the Field and in the Territory in accordance with this Agreement would infringe such Patent Right in the absence of a license thereunder; provided, for clarity, that the performance of activities as permitted under the safe harbor provision provided in 35 U.S.C. § 271(e)(1) (or other applicable safe harbor exemptions in other countries outside the United States) shall not be deemed to trigger the date under the foregoing clause (b).

6.5.3 Management of In-Licenses. Licensor shall not, and shall cause its Affiliates not to, enter into any subsequent agreement or understanding with any Third Party to an In-License to which such Licensor or any of its Affiliates is a party that modifies, amends or terminates any such In-License, or waives any right or obligation thereunder, in any way that would adversely affect in any material respect Licensee's rights or interests under this Agreement, including by increasing any of Licensee's obligations or otherwise agreeing to any covenants or obligations imposed on Licensee that would adversely impact Licensee's business outside of this Agreement, in each case, without Licensee's prior written consent, not to be unreasonably withheld, conditioned or delayed. Licensor shall not, and Licensor shall cause its Affiliates not to, commit any acts or permit the occurrence of any omissions that would cause a material breach or termination of any such In-License that would adversely affect in any material respect Licensee's rights or interests under this Agreement.

[64] Note to Draft: Change to "Licensee" if Alnylam is the Licensee.
[65] Note to Draft: Change to "Licensee" if Alnylam is the Licensee.
[66] Note to Draft: Change to "Licensee" if Alnylam is the Licensee.
[67] Note to Draft: Delete bracketed language if Alnylam is the Licensee.

6.5.4 In-Licenses. Each Party acknowledges and agrees that the sublicenses and other rights granted by the other Party to such first Party in this Agreement are subject to the terms of any In-Licenses to which such other Party or any of its Affiliates is a party. Each Party granted a sublicense pursuant to this Agreement under any of the In-Licenses of the other Party (or any of its Affiliates) (the Party granted a sublicense, the "**Sublicensed Party**," and the Party granting the sublicense, the "**Sublicensor Party**") shall comply with, and perform and take such actions as may be required to allow the Sublicensor Party to comply with, all applicable terms and conditions of the In-Licenses of the Sublicensor Party to the extent (a) applicable to (i) the Sublicensed Party's rights or obligations relating to the Development, Manufacture or Commercialization of Collaboration Products under this Agreement or (ii) the filing, prosecution, maintenance, extension, defense, enforcement or the further sublicensing of the Licensor Technology (if Licensor is the Sublicensor Party) or the Licensee Technology (if Licensee is the Sublicensor Party) to the extent relevant to the Sublicensed Party's rights or obligations relating to the Development, Manufacture or Commercialization of Collaboration Products under this Agreement, and (b) the Sublicensed Party has been given written notice or provided a copy of such terms and conditions on or before the later of (i) the Effective Date and (ii) the date on which such In-License is first required to have been provided to the Sublicensed Party hereunder, including any such terms and conditions relating to sublicensing, patent matters, confidentiality, reporting, audit rights, indemnification and diligence. Without limiting the foregoing, (x) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of any In-License and (y) each Sublicensed Party shall prepare and deliver to the Sublicensor Party any reports required under the applicable In-Licenses of the Sublicensor Party sufficiently in advance to enable the Sublicensor Party to comply with its obligations under the applicable In-Licenses, to the extent that the Sublicensed Party had been made aware of such provisions sufficiently in advance of the date on which such compliance is required in order for such Sublicensed Party to properly prepare such reports.

6.5.5 [**Excluded Agreements.** Notwithstanding anything herein to the contrary, Licensee acknowledges that certain Patent Rights and Information under which Licensor has rights are in-licensed by Licensor under the Excluded Agreements. It is understood and agreed that no sublicense is granted to Licensee by Licensor under the Excluded Agreements pursuant to this Agreement, and that no Patent Rights or Information licensed to Licensor under the Excluded Agreements will be Controlled by Licensor under this Agreement. Licensor shall be solely responsible for, and shall solely bear, all costs arising under or in connection with any Excluded Agreement.][68]

[68] Note to Draft: Include this provision if Alnylam is the Licensor.

6.6 Confirmatory Patent License. Each Party shall, if requested to do so by the other Party, promptly enter into confirmatory license agreements in the form or substantially the form reasonably requested by such other Party for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as the requesting Party considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Licensor and Licensee shall have the same rights in respect of the respective intellectual property and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

6.7 Exclusivity.

6.7.1 Exclusivity.

(a) Target Exclusivity. During the Term, subject to Section 6.7.2 and Section 6.7.3 and the remainder of this Section 6.7.1(a), and in the case of Alnylam, except as and to the extent set forth in the Existing [Licensor][Licensee][69] Third Party Agreements, and in the case of Regeneron except as and to the extent set forth in the Existing [Licensor][Licensee][70] Third Party Agreements, in each case, as existing as of the Effective Date (as defined in the Master Agreement) of the Master Agreement, each Party shall not, and shall cause its Affiliates not to, (i) directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization, any Competing Product in the Field in any country in the Territory, or (ii) license, authorize or appoint any Third Party to directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization, any Competing Product in the Field in any country in the Territory.

(A) The provisions of Section 6.7.1(a)(i) and (ii) shall not apply to any Competing Product Directed to the Target using or incorporating only Non-Relevant Organ Delivery Technology; provided that such Competing Product using or incorporating such Non-Relevant Organ Delivery Technology is not administered to or used in (or developed or designed for use or administration in) the Relevant Organ through any route of administration [(including when administered [intrathecally] [intraocularly][71])][72].

[69] Note to Draft: To be updated based on whether Alnylam is Licensor or Licensee.

[70] Note to Draft: To be updated based on whether Regeneron is Licensor or Licensee.

[71] Note to Draft: Include “intrathecally” if the Target is a CNS Target. Include “introcularly” if the Target is an Eye Target.

[72] Note to Draft: Include this bracketed language only if the Target is a CNS Target or an Eye Target.

(B) [The provisions of Section 6.7.1(a)(i) and (ii) shall not apply to any Permitted Competing Products.] [73]

(b) siRNA Sequence Exclusivity. Without limiting the provisions of Section 6.7.1(a), during the Term, [Licensor][Licensee][74] shall not, and shall cause its Affiliates not to, (i) directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization any siRNA that includes the same nucleotide sequence (or a different nucleotide sequence that functionally targets the same nucleotide sequence of the messenger RNA) as a Collaboration Product except [***] (ii) license, authorize or appoint any Third Party to directly or indirectly, develop, commercialize or manufacture for purposes of development or commercialization any siRNA that includes the same nucleotide sequence (or a different nucleotide sequence that functionally targets the same nucleotide sequence of the messenger RNA) as a Collaboration Product except for [***] provided that in each case ((i)-(ii)) [***].

[73] Note to Draft: Include this provision only if the Target was a CNS Target or an Eye Target under the Master Agreement and there is a Permitted Competing Product hereunder.

[74] Note to Draft: Term to be selected based on whether Alnylam is Licensor or Licensee.

(c) Continuation From Master Agreement. In the event that prior to entering into this Agreement there was a "Competing Program" or "Acquisition Product" with respect to the Target pursuant to Section 5.7.2 of the Master Agreement, then such "Competing Program" or "Acquisition Product" shall also be a Competing Program or Acquisition Product, as applicable, for purposes of this Agreement, and the provisions of Sections 6.7.2 and 6.7.3 shall apply; provided, however, that if the applicable Acquirer and its Affiliates (other than the Pre-Existing Affiliates) was allowed to continue to develop, manufacture, commercialize and exploit a given Competing Program under the Master Agreement in accordance with Section 5.7.2(d) of the Master Agreement, then such Acquirer and its Affiliates (other than Pre-Existing Affiliates) shall have the right to continue to develop, manufacture, commercialize and exploit such Competing Program hereunder without being in violation of the provisions of Section 6.7.1(a); provided that the Acquirer shall or shall cause the Acquired Party to (i) continue to fulfill its obligations under this Agreement in all respects, (ii) ensure that the conduct of Competing Program activities is completely independent of the activities conducted under or in connection with this Agreement, (iii) ensure that all Competing Program activities (A) do not use, access or incorporate and are not based on any Licensor Know-How, Licensee Know-How or other Confidential Information, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1, and (B) are not covered by and do not incorporate or reference the Licensor Patents or Licensee Patents (or any Information or inventions disclosed in any of the foregoing), and (iv) establish reasonable internal safeguards designed to prevent any Licensor Know-How, Licensee Know-How or other Confidential Information from being disclosed to, or otherwise utilized by, the Acquirer or any of its Affiliates (other than Pre-Existing Affiliates), in connection with the Competing Program, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1.

6.7.2 Change of Control and Acquired Competing Programs and Products.

(a) If, during the Term, (i) there is a Change of Control of a Party (such Party, the "**Acquired Party**") and as of the effective date of such Change of Control, a Third Party described in the definition of "Change of Control" or any of its Affiliates (other than the Acquired Party, or the Acquired Party's Pre-Existing Affiliates) (the "**Acquirer**") is engaged, directly or indirectly, in any activities that, if carried out by the Acquired Party, would be a breach of the exclusivity obligations set forth in Section 6.7.1 (such activities, a "**Competing Program**"), or (ii) as the result of an acquisition of a Third Party or the assets of a Third Party by a Party or one or more of its Affiliates (the "**Acquiring Party**"), the Acquiring Party directly or indirectly acquires rights to a Competing Product in the Field that would be a breach of the exclusivity obligations set forth in Section 6.7.1 (each such Competing Product, an "**Acquisition Product**" and each transaction described in subsection (i) or (ii), a "**Third Party Acquisition**"); then, the

Acquired Party or Acquiring Party, as applicable, shall give the other Party (the "**Non-Acquiring Party**") express written notice thereof within ten (10) Business Days after the closing of such Third Party Acquisition and furthermore the Acquired Party or Acquiring Party, as applicable, shall in its sole discretion do one of the following after the closing of such Third Party Acquisition: (w) by the later of six (6) months after (i) such closing, (ii) the expiration of the Divestment Period pursuant to Section 6.7.2(b) and (iii) the date on which the Parties cease negotiations pursuant to Section 6.7.2(c), as applicable, terminate all development, commercialization and manufacture for purposes of development or commercialization, with respect to such Competing Program or Acquisition Product, as applicable (other than Clinical Trials that a Regulatory Authority requires the Acquired Party or Acquiring Party, as applicable, to continue, which may be continued for no more than twelve (12) months after such closing or such longer period as such Regulatory Authority requires), and deliver to the Non-Acquiring Party a notice of such termination, which notice shall include a covenant that no further development, commercialization or manufacture for purposes of development or commercialization, with respect to such Competing Program or Acquisition Product shall be performed by or on behalf of such Acquired Party or Acquiring Party, as applicable, or any of its Affiliates, to the extent the provisions of Section 6.7.1 would have prohibited such activities; provided, that an Acquired Party or Acquiring Party, as applicable, shall not be prohibited from later divesting its rights in such terminated Competing Program or Acquisition Product, as applicable, whether pursuant to the provisions of this Section 6.7.2 or otherwise; (x) divest its rights in the Competing Program or Acquisition Product to a Third Party pursuant to Section 6.7.2(b); (y) offer the Competing Product Option to the Non-Acquiring Party pursuant to Section 6.7.2(c) or (z) if applicable, exercise the right to continue the Competing Program as set forth in Section 6.7.2(d). If the Acquired Party or Acquiring Party fails to comply with one of the foregoing clauses (w), (x), (y) or (z), then, unless the Parties otherwise agree in writing, the Acquired Party or Acquiring Party, as applicable, shall be in breach of Section 6.7.1.

(b) If the Acquired Party or Acquiring Party, as applicable, chooses to divest its rights in the Competing Program or Acquisition Product, as applicable, to a Third Party, the Acquired Party or Acquiring Party, as applicable, shall commit in writing to the Non-Acquiring Party, within forty-five (45) days of the later of (i) the closing of such Third Party Acquisition and (ii) the date on which the Parties cease negotiations pursuant to Section 6.7.2(c), as applicable, to divest such Competing Program or Acquisition Product, as applicable, to a Third Party within one hundred eighty (180) days after the closing of the Third Party Acquisition, and shall do so within such one hundred eighty (180)-day period; provided, that if the Acquired Party or Acquiring Party, as applicable, fails to complete such divestiture within such one hundred eighty (180)-day period, but can demonstrate to the Non-Acquiring Party's reasonable satisfaction that it used commercially reasonable efforts to effect such divestiture within such one hundred eighty (180)-day period, then, unless otherwise required by Applicable Law, such one hundred eighty (180)-day period shall be extended for such additional reasonable period thereafter as is necessary to

enable such Competing Program or Acquisition Product, as applicable, to be in fact divested, not to exceed an additional one hundred and eighty (180) days; provided, however, that such period shall be extended for such period as is necessary to obtain any governmental or regulatory approvals required to complete such divestiture, provided that the Acquired Party or Acquiring Party, as applicable, is using good faith efforts to obtain such approvals (such period, the "**Divestment Period**"). If the Acquired Party or Acquiring Party, as applicable, does not complete the divestiture within the Divestment Period, then the Acquired Party or Acquiring Party, as applicable, shall terminate such Competing Program or Acquisition Product, as applicable pursuant to Section 6.7.2(a), or, provided such Competing Program or Acquisition Product has not previously been the subject of a Competing Product Option, offer the Non-Acquiring Party the option to include the Competing Program or Acquisition Product as a Collaboration Product under this Agreement pursuant to Section 6.7.2(c). Any divestiture of rights under this Section 6.7.2(b) shall not permit the Acquired Party or Acquiring Party, as applicable, or its Affiliates to retain any rights in (other than the right to receive payments) or involvement with the Competing Program or Acquisition Product, as applicable, including rights to direct or influence the course of development or commercialization thereof, or to contribute or receive nonpublic know-how or information of any sort with respect thereto (other than reports showing the basis for calculating payments made to the Acquired Party or Acquiring Party, as applicable, and the right to audit the accuracy of such reports); provided, that the Acquired Party or Acquiring Party, as applicable, may continue to supply the applicable Competing Product to the acquirer and provide other transitional services for a reasonable transitional period until the acquirer is able to establish its own source of supply of such Competing Product and provider for such services. If the Acquired Party or Acquiring Party, as applicable, elects to divest the Competing Program or Acquisition Product, the Acquired Party or Acquiring Party, as applicable shall not be precluded under Section 6.7.1 from conducting any activities (either directly, or with or through any Third Party) with respect to such Competing Program or Acquisition Product during the applicable Divestment Period; provided, that any such activities are subject to appropriate firewall procedures to segregate such activities (and the personnel conducting such activities) from the activities performed by or on behalf of the Acquired Party or Acquiring Party, as applicable, pursuant to this Agreement to ensure that no Confidential Information of the Non-Acquiring Party and no other information generated under this Agreement is used in connection with such Competing Program or Acquisition Product.

(c) If the Acquired Party or Acquiring Party, as applicable, chooses to offer to the Non-Acquiring Party the option to include the Competing Program or Acquisition Product as a Collaboration Product under this Agreement (the "**Competing Product Option**"), the Acquired Party or Acquiring Party, as applicable, shall provide a Competing Product Option Data Package to the Non-Acquiring Party within thirty (30) days after the closing of such Third Party Acquisition. If the Non-Acquiring Party is interested, in its sole discretion, in exercising

the Competing Product Option, it shall provide written notice thereof to the Acquired Party or Acquiring Party, as applicable, within thirty (30) days of receipt of the Competing Product Option Data Package and, promptly thereafter, the Parties shall negotiate in good faith the terms pursuant to which such Competing Program or Acquisition Product would be included as a Collaboration Product under this Agreement. If the Parties do not reach agreement within ninety (90) days after beginning such good faith negotiations, then the Acquired Party or Acquiring Party, as applicable, shall either terminate such Competing Program or Acquisition Product or divest its rights in such Competing Program or Acquisition Product pursuant to this Section 6.7.2.

(d) Notwithstanding anything in this Section 6.7.2 to the contrary, if during the Term there is a Third Party Acquisition as described in Section 6.7.2(a)(i), then the Acquirer and its Affiliates (other than Pre-Existing Affiliates) shall have the right to continue to develop, manufacture, commercialize and exploit such Competing Program without being in violation of the provisions of Section 6.7.1(a) (or the provisions of Section 6.7.1(b), but with respect to Section 6.7.1(b), this Section 6.7.2(d) shall only apply to a given Competing Product of a Competing Program that has initiated (i.e., first dosing of first patient) a Phase 2 Clinical Trial at the time of the closing of the applicable Third Party Acquisition); provided that the Acquirer shall or shall cause the Acquired Party to (i) continue to fulfill its obligations under this Agreement in all respects, (ii) ensure that the conduct of Competing Program activities is completely independent of the activities conducted under or in connection with this Agreement, (iii) ensure that all Competing Program activities (A) do not use, access or incorporate and are not based on any Licensor Know-How, Licensee Know-How or other Confidential Information, for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1, and (B) are not covered by and do not incorporate or reference the Licensor Patents or Licensee Patents (or any Information or inventions disclosed in any of the foregoing), and (iv) establish reasonable internal safeguards designed to prevent any Licensor Know-How, Licensee Know-How or other Confidential Information from being disclosed to, or otherwise utilized by, the Acquirer or any of its Affiliates (other than Pre-Existing Affiliates), in connection with the Competing Program for so long as such Confidential Information remains subject to the confidentiality and non-use obligations under Section 9.1.

(e) Notwithstanding anything in this Agreement to the contrary, following the closing of a Change of Control of an Acquired Party, the Parties agree that (x) the Non-Acquiring Party shall not obtain rights or access to the Patent Rights or Information controlled by the Acquirer or any of the Affiliates of such Acquirer (other than the Acquired Party and its Affiliates that exist immediately prior to the closing of such Change of Control and any successor thereto (such Affiliates of the Acquired Party, the "**Pre-Existing Affiliates**")) at the time of such closing (and improvements to such Patent Rights or Information) and any other Patent Rights or Information first acquired or in-licensed by such Acquirer (or any of its Affiliates, other than the Acquired Party and its Pre-Existing Affiliates) from a Third Party after the closing of the Change

of Control transaction (and improvements thereto) (so that, for clarity, none of the foregoing will be treated as Controlled by Alnylam or any of its Affiliates, or by Regeneron or any of its Affiliates, based on which Party is the Acquired Party); and (y) the Acquirer and its Affiliates (other than the Acquired Party and its Pre-Existing Affiliates) shall not obtain rights or access to the Patent Rights or Information controlled by the Non-Acquiring Party or any of its Affiliates pursuant to this Agreement, other than in connection with the Exploitation of any Collaboration Products as provided under this Agreement; provided that clause (x) of this Section 6.7.2(e) shall not apply to any Patent Rights or Information controlled by the Acquirer or any of its Affiliates to the extent such Patent Right or Information (i) is used by or on behalf of the Acquired Party or any of its Affiliates in performing any of the Acquired Party's obligations under this Agreement; (ii) is incorporated into any Collaboration Product by or on behalf of the Acquired Party or any of its Affiliates; or (iii) was generated after the closing of such Change of Control through any use of, or access to, any Licensor Know-How (with respect to Licensor as the Acquired Party) or any Licensee Know-How (with respect to Licensee as the Acquired Party) or is otherwise Covered by any Licensor Patent (with respect to Licensor as the Acquired Party) or any Licensee Patent (with respect to Licensee as the Acquired Party); provided that, (A) with respect to Licensor as the Acquired Party, if the Acquirer or any of its Affiliates was party to an agreement with Licensor or any Pre-Existing Affiliate on or prior to the date of such Change of Control pursuant to which the Acquirer or such Affiliates received a license to any Information or Patent Rights controlled by Licensor or its Pre-Existing Affiliates other than any Licensor Product-Specific Know-How or Licensor Product-Specific Patents, then this clause (iii) shall not apply to any Patent Rights or Information controlled or generated by Acquirer or such Affiliates under such agreement prior to such Change of Control that were not Controlled by Licensor or any Pre-Existing Affiliate or (B) with respect to Licensee as the Acquired Party, if the Acquirer or any of its Affiliates was party to an agreement with Licensee or any Pre-Existing Affiliate on or prior to the date of such Change of Control pursuant to which the Acquirer or such Affiliates received a license to any Information or Patent Rights controlled by Licensee or its Pre-Existing Affiliates other than any Licensee Product-Specific Know-How or Licensee Product-Specific Patents, then this clause (iii) shall not apply to any Patent Rights or Information controlled or generated by Acquirer or such Affiliates under such agreement prior to such Change of Control that were not Controlled by Licensee or any Pre-Existing Affiliate. Without limiting the foregoing, in all cases the Non-Acquiring Party's rights in all Patent Rights and Information Controlled by the Acquired Party or any of its Pre-Existing Affiliates, or any of their respective successors, and all improvements thereto shall remain licensed to such Non-Acquiring Party after the date of the closing of such Change of Control in accordance with and subject to the terms and conditions of this Agreement and shall not be affected in any manner by virtue of such Change of Control.

6.7.3 Regeneron Exceptions. Notwithstanding the exclusivity obligation in Section 6.7.1 [or the exclusive license grants contained in Section 6.1][75]:

(a) Regeneron reserves the right to grant licenses to Third Parties to use intellectual property owned or otherwise controlled by Regeneron or its Affiliates related to research-enabling technologies, discovery-enabling technologies or manufacturing-related technologies, including [Licensor][76] Technology, and rights to Regeneron Mice, but excluding [Licensee][77] Technology, [Licensor][78] Product-Specific Patents, and [Licensor][79] Product-Specific Know-How ("**Excluded Collaboration Technology**"), which licenses during the Term, may be for general purposes not specific to Competing Products (i.e., that is not specific to the Manufacture of any particular Competing Product), but which may involve the exploitation of Competing Products in the Field, and such grant and any associated disclosure or provision of such intellectual property or provision of technical assistance using only such intellectual property in connection therewith shall not constitute a breach of this Agreement (including Section 6.7.1); provided that Regeneron and its Affiliates will not otherwise actively assist any Third Party (other than through the grant of such license or provision of such technical assistance) in developing or commercializing any Competing Product in the Field if doing so would not comply with Section 6.7.1, but, for clarity, may receive license fees, milestones and royalties in connection with exploitation by Third Parties of any Competing Products in the Field generated by such Third Parties.

(b) Regeneron reserves the right to grant licenses to Third Parties to use any clinical, genomic, and molecular data maintained by the Regeneron Genetics Center, other than any such data that is Excluded Collaboration Technology, for any purpose, which may involve activities with respect to Competing Products in the Field, and such grant and any associated disclosure or provision of such data or provision of technical assistance without the use of Excluded Collaboration Technology in connection therewith shall not constitute a breach of this Agreement (including Section 6.7.1); provided that, Regeneron and its Affiliates will not otherwise actively assist any Third Party (other than through the grant of such license or provisions of such technical assistance) in developing or commercializing any Competing Product in the Field if doing so would not comply with Section 6.7.1, but, for clarity, may receive license fees, milestones and royalties in connection with exploitation by Third Parties of any Competing Products in the Field generated by such Third Parties.

[75] Note to Draft: Delete this bracketed language if Regeneron is Licensee.
[76] Note to Draft: Change this bracketed language to "Licensee" if Regeneron is Licensee.
[77] Note to Draft: Change this bracketed language to "Licensor" if Regeneron is Licensee.
[78] Note to Draft: Change this bracketed language to "Licensee" if Regeneron is Licensee.
[79] Note to Draft: Change this bracketed language to "Licensee" if Regeneron is Licensee.

(c) The Parties acknowledge and agree that nothing in Section 6.7.1 prevents or limits Regeneron's or its Affiliate's rights to (i) settle any enforcement action or proceeding (including any counterclaim in any such action or proceeding), declaratory judgment action or similar action or claim, or any other litigation or proceeding involving an allegation of infringement or other violation of intellectual property or the invalidity or enforceability of any Patent Right owned or otherwise controlled by Regeneron or any of its Affiliates (other than with respect to intellectual property controlled by Regeneron or its Affiliates as a licensee of Alnylam under this Agreement), including by granting licenses or other rights under any such Patent Right to Third Parties in connection therewith or (ii) enter into an agreement to preempt, and thereby avoid the initiation of, any of the actions, proceedings, claims or other litigation set forth in clause (i), including by granting licenses or other rights under any such Patent Right to Third Parties in connection therewith; provided that, in either case ((i) or (ii)), neither Regeneron nor any of its Affiliates may grant a license or other right under any such Patent Right to a Third Party to make, have made, use, offer to sell, sell or import a generic version of a Collaboration Product in the Field, including any Generic Product, except pursuant to ARTICLE 8.

6.8 [***]. Notwithstanding anything to the contrary contained herein, the provisions of this Section 6.8 shall apply.

6.8.1 [***]

6.8.2 [***]

6.8.3 [***]

6.8.4 [***]

6.8.5 Notwithstanding anything to the contrary set forth in ARTICLE 9, Licensee may disclose any Confidential Information relating to this Agreement and the activities hereunder (including the Target and Collaboration Products) [***].

6.8.6 For purposes of this Agreement, the following defined terms shall have the following meanings:

(a) [***]

(b) [***]

(c) [***]

Article 7
PAYMENTS

7.1 Royalty Payments.

7.1.1 Royalties. From and after the First Commercial Sale of a Collaboration Product in a country, for each Calendar Quarter during the applicable Royalty Term for such Collaboration Product in such country, Licensee shall make royalty payments to Licensor on aggregate worldwide annual Net Sales of such Collaboration Product, on a Collaboration Product-by-Collaboration Product basis, at the following royalty rates (the "**Royalties**"):

Aggregate Annual Net Sales of a given Collaboration Product in the Territory in a Calendar Year	**Royalty Rate**
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] and up to and including [***] in a given Calendar Year	[***]
On the portion of aggregate annual Net Sales of such Collaboration Product in the Territory over [***] in a given Calendar Year	[***]

7.1.2 Royalty Rate Reductions. Notwithstanding the provisions of Section 7.1.1, if during the Royalty Term for a Collaboration Product in a country:

[***]

7.1.3 [**Manufacturing Technology Transfer Costs Reduction.** Subject to Section 7.1.5, [***]

7.1.4 In-License Payment Adjustments.

(a) Existing Licensor In-Licenses. [***]

(b) Existing Licensee In-Licenses. Subject to Section 7.1.5 [***].

(c) Product-Related In-Licenses. Subject to Section 7.1.5 [***].

7.1.5 Limit on Reductions or Increases.

[***]

7.1.6 Royalty Reports. Within [***] days following the end of each Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale of any Collaboration Product occurs in any country, (a) Licensee shall provide to Licensor a written report (in electronic form) setting forth, for such Calendar Quarter, (i) the Net Sales of each Collaboration Product, (ii) Collaboration Product quantities sold, (iii) gross Collaboration Product sales and a reasonably detailed accounting of the deductions from gross sales permitted by the definition of Net Sales and (iv) the amount of any In-License Payments paid by Licensee or any of its Affiliates and (b) Licensor shall provide to Licensee a written report (in electronic form) setting forth, for such Calendar Quarter, the amount of any In-License Payments paid by Licensor or any of its Affiliates. Within [***] days following the end of each Calendar Quarter, Licensee shall deliver the Royalties payment, if any, due to Licensor under Section 7.1.1 for the applicable Calendar Quarter. Such reports shall be broken down on a country-by-country basis with respect to the Major Market Countries and Licensee shall report the other countries of the Territory in a consolidated manner.

7.1.7 Unlicensed Components. For clarity, the Parties shall not share any revenues from any Unlicensed Component of a Collaboration Product, either through sharing of Third Party Transaction Proceeds, or payment of royalties or milestones, or otherwise (provided that with respect to Net Sales, the Parties agree that any allocation shall be in accordance with the definition of Net Sales).

7.2 Milestones.

7.2.1 Development and Commercialization Milestones. Subject to the terms of this Section 7.2, Licensee will notify Licensor promptly (but in all cases within thirty (30) days) following the first achievement by Licensee under this Agreement of each milestone event described below in this 7.2.1 with respect to a given New Collaboration Product to achieve such milestone event, and Licensee shall thereafter pay the applicable amounts set forth below associated with the applicable milestone event in accordance with Section 7.2.3 (each, a "**Non-Rare Disease Milestone Payment**"):

Development Milestone Event		Milestone Payment
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
Commercial Milestone Event		**Milestone Payment**
4.	[***]	[***]
5.	[***]	[***]
6.	[***]	[***]
7.	[***]	[***]

Each of the foregoing Milestone Payments in this Section 7.2.1 shall be payable a maximum of one (1) time for a given New Collaboration Product as set forth in the foregoing chart (i.e., a maximum of seven (7) Milestone Payments may be made pursuant to this Section 7.2.1 for a given New Collaboration Product), and no additional Milestone Payments shall be due hereunder for subsequent or repeated achievement of such milestone event for a given New Collaboration Product. For the avoidance of doubt, (i) the maximum amount payable by Licensee pursuant to this Section 7.2.1 for a given New Collaboration Product is [***], assuming that each of the milestone events in this Section 7.2.1 are achieved for such New Collaboration Product and (ii) no Milestone Payments shall be payable for any Collaboration Product that is not a New Collaboration Product.

[***]

7.2.2 Rare Disease Milestones. Subject to the terms of this Section 7.2 and notwithstanding Section 7.2.1, in the event a given New Collaboration Product is being Developed for a Rare Disease (a "**Rare Disease New Collaboration Product**"), in lieu of the Milestone Payments set forth in Section 7.2.1, Licensee will pay Licensor for achievement of the milestones set forth in this Section 7.2.2. Licensee will notify Licensor promptly (but in all cases within thirty (30) days) following the first achievement by Licensee under this Agreement of each milestone event described below in this Section 7.2.2 with respect to a given Rare Disease New Collaboration Product to achieve such milestone event, and Licensee shall thereafter pay the applicable amounts set forth below associated with the applicable milestone event in accordance with Section 7.2.3 (each, a "**Rare Disease Milestone Payment**"):

Commercial Milestone Event		Milestone Payment
1.	[***]	[***]
2.	[***]	[***]

Each of the foregoing Milestone Payments in this Section 7.2.2 shall be payable a maximum of one (1) time for a given Rare Disease New Collaboration Product as set forth in the foregoing chart (i.e., a maximum of two (2) Milestone Payments may be made pursuant to this Section 7.2.2

for a given Rare Disease New Collaboration Product), and no additional Rare Disease Milestone Payments shall be due hereunder for subsequent or repeated achievement of such milestone event for a given Rare Disease New Collaboration Product. For the avoidance of doubt, (i) the maximum amount payable by Licensee pursuant to this Section 7.2.2 for a given Rare Disease New Collaboration Product is [***], assuming that each of the milestone events in this Section 7.2.2 are achieved and (ii) no Milestone Payments shall be payable for any Collaboration Product that is not a Rare Disease New Collaboration Product.

7.2.3 Notwithstanding the foregoing, if a New Collaboration Product is a Rare Disease New Collaboration Product but is also Developed for a non-Rare Disease, and prior to the achievement of any of the Rare Disease Milestone Payment events with respect to such Rare Disease New Collaboration Product, a Development Milestone Event is achieved under Section 7.2.1 with respect to such Rare Disease New Collaboration Product for such non-Rare Disease, then such New Collaboration Product shall be subject to the provisions of Section 7.2.1 and not this Section 7.2.2. In such case, at the time that such New Collaboration Product achieves the first Development Milestone Event for which a Milestone Payment is payable pursuant to Section 7.2.1, Licensee shall also be deemed to have achieved any earlier Development Milestone Events pursuant to Section 7.2.1 for which Development Milestones were not previously paid with respect to such New Collaboration Product (e.g., if the first Development Milestone that is achieved for such Collaboration Product for a non-Rare Disease is [***], then each of Development Milestones #1 and #2 from Section 7.2.1 will be deemed achieved by Licensee at the such time).

7.2.4 Invoice and Payment of Milestone Payments. Following receipt of notification by Licensee to Licensor that Licensee has achieved the applicable milestone event triggering a milestone payment pursuant to Section 7.2.1 or 7.2.2, as applicable, Licensor shall invoice Licensee for the applicable milestone payment, and, subject to Section 7.10, Licensee shall pay each milestone payment [***] days after receipt of the invoice therefor.

7.2.5 One-Time Only Payments. For clarity, a given Collaboration Product shall only be eligible for milestone payments under one of Section 7.2.1 or 7.2.2, but not both.

7.3 Third Party Transaction Proceeds.

[***]

7.4 [**Other Costs.** [***]

7.5 [**Adjustments to FTE Rates.** [***]

7.6 No Double Counting. Notwithstanding anything to the contrary contained herein, no cost or expense shall be included as an Alnylam Specific Activities Costs (or any component

thereof) or in the calculation of Net Sales (or any component thereof), if inclusion therein would result in a duplication or double-counting of the same cost or expense, either hereunder or under the Master Agreement or any other License Agreement or Co-Co Collaboration Agreement.

7.7 Invoices and Documentation. The Parties shall approve the form of any necessary documentation relating to any Royalty, milestone or other payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder. Unless otherwise agreed by the Parties, the financial data in the reports will include calculations in local currency and Dollars.

7.8 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in Dollars. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars at the average rate of exchange for the Calendar Quarter to which such payment relates using the arithmetic mean of the daily rate of exchange, as reported in *Thomson Reuters Eikon* (or any successor thereto) or any other source as agreed to by the Parties.

7.9 Taxes. Either Party may withhold from payments due to the other Party amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. In such case, the payor Party will provide the payee Party all relevant documents and correspondence, and will also provide to the payee Party any other cooperation or assistance on a commercially reasonable basis as may be necessary to enable the payee Party to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. The payor Party will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Apart from any withholding permitted under this Section 7.9 and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies. Notwithstanding the foregoing, if, as a result of a Withholding Action by the paying Party (including any assignee or successor), any withholding or deduction of or on account of taxes, duties, levies, imposts, assessments, deductions, fees and other similar charges ("**Withholding**") is required by Applicable Law and the amount of such Withholding exceeds the amount of Withholding that would have been required if the paying Party had not committed the Withholding Action, then the paying Party shall pay an additional amount to the receiving Party such that, after Withholding from the payment and such additional amount, the receiving Party receives the same amount as it would have received from the paying Party absent such Withholding Action by the paying Party. For the avoidance of doubt, if as a result of a Withholding Action by a receiving Party (including any assignee or successor) the amount of

Withholding under the law of the applicable jurisdiction exceeds the amount of such Withholding that would been required in the absence of such Withholding Action by the receiving Party, the paying Party shall be required to pay any additional amount only to the extent that the paying Party would be required to pay any additional amount to the receiving Party pursuant to the preceding sentence if the receiving Party had not committed such Withholding Action. For purposes of this Section 7.9, "**Withholding Action**" by a Party means (i) a permitted assignment or sublicense of this Agreement (in whole or in part) by such Party to an Affiliate or a Third Party outside of the United States; (ii) the exercise by such Party of its rights under this Agreement (in whole or in part) through an Affiliate or Third Party outside of the United States (or the direct exercise of such rights by an Affiliate of such Party outside of the United States); (iii) a redomiciliation of such Party, an assignee or a successor to a jurisdiction outside the United States; and (iv) any action by such Party that causes this Agreement or any payment to become subject to tax in a jurisdiction outside of the United States or subject any payments to Withholding in any jurisdiction that would not have been required absent such Withholding Action.

7.10 Resolution of Payment Disputes. In the event there is a dispute relating to any payment obligations or reports hereunder, the Party with the dispute shall provide the other Party with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. If the Parties are unable to resolve such payment dispute within such period then the matter shall be resolved pursuant to Section 13.5. The Parties agree that if there is a dispute regarding any payment amount, only the disputed amount shall be withheld from the payment, and the undisputed amount shall be paid within the applicable timeframes.

7.11 Late Fee. A late fee [***] as reported on *Thomson Reuters Eikon* (or any successor thereto) (or another source agreed to by the Parties) on the date that the applicable payment was due may be charged by the Party to whom payment is due with respect to any payment amount from the date such payment amount was originally due under the terms of this Agreement until such payment amount is actually paid by one Party to another Party unless such payment amount is disputed pursuant to Section 7.10, in which case the foregoing late fee shall commence on the date such dispute is resolved.

7.12 Books and Records. Each Party shall (a) keep proper books of record and account in which full, true and correct entries (in conformity with Accounting Standards) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement; (b) keep such books of record and account for at least [***] Calendar Years following the Calendar Year to which they pertain (or such longer period to the extent required by Applicable Law) and (c) keep such books of record and account to the extent related to this Agreement in a readily available and organized form to allow an independent auditor to verify the accuracy of all financial, accounting

and numerical information provided in an efficient manner. To the extent a Party is not in compliance with clause (c) of this Section 7.12, such Party shall be responsible for any additional fees charged by the independent auditor to the other Party as a result of additional time spent by the independent auditor assembling or organizing such information.

7.13 Audits and Adjustments.

7.13.1 Audit. Each Party shall have the right, upon no less than [***] days' advance written notice and at such reasonable places, times and intervals and to such reasonable extent as such Party shall request, not more than once during any Calendar Year, to have the books of record and account of the other Party to the extent relating to this Agreement for the preceding [***] Calendar Years audited by an independent and nationally recognized accounting firm of its choosing and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided, that absent evidence of fraud, gross negligence or willful misconduct no period may be subjected to audit more than [***] time.

7.13.2 Results; Costs; Confidentiality. The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party by notice to the other Party within [***] days after delivery. [***] Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the results of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in ARTICLE 9. At the request of the Party being audited prior to the audit, the auditing Party shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such accounting firm to retain all such information in confidence pursuant to such confidentiality agreement.

7.13.3 Reconciliation. If any examination or audit of the records described above discloses an overbilling or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.13.2, the Party that over-billed or underpaid shall pay the same to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to Section 7.13.1.

7.13.4 Binding and Conclusive. Upon the expiration of the three (3) year period following the end of any Calendar Year, the calculation of the amounts payable with respect to such Calendar Year shall be binding and conclusive upon the Parties.

7.14 Accounting Standards. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with Accounting Standards, as generally and consistently applied.

Article 8
INTELLECTUAL PROPERTY

8.1 Ownership of Intellectual Property.

8.1.1 Ownership of Technology. Subject to Section 3.4.1(b) and Section 8.1.2, as between the Parties: (a) Licensee shall own and retain all right, title and interest in and to any and all (i) Licensee Collaboration IP and (ii) other Information, inventions, Patent Rights, and other intellectual property rights that are owned or otherwise Controlled by Licensee, its Affiliates or its or their Sublicensees, including the Licensee Technology, and (b) Licensor shall own and retain all right, title and interest in and to any and all (i) Licensor Collaboration IP and (ii) other Information, inventions, Patent Rights, and other intellectual property rights that are owned or otherwise Controlled by Licensor, its Affiliates or its or their Sublicensees, including the Licensor Technology. Licensee shall own and retain all right, title and interest in and to any and all Licensee Background Technology. Licensor shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to Licensee, without additional compensation, all right, title and interest in and to any Licensee Background Technology Improvements as is necessary to fully effect the ownership thereof as provided for in this Section 8.1.1. Licensor shall own and retain all right, title and interest in and to any and all Licensor Background Technology. Licensee shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to Licensor, without additional compensation, all right, title and interest in and to any Licensor Background Technology Improvements as is necessary to fully effect the ownership thereof as provided for in this Section 8.1.1.

8.1.2 Ownership of Joint Collaboration IP. Subject to Section 3.4.1(b), as between the Parties, the Parties shall each own an equal, undivided interest in and to any and all Joint Collaboration IP. Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates and Sublicensees to so disclose, the development, making, conception or reduction to practice of any Joint Collaboration IP. Subject to the licenses and rights of reference granted under Section 6.1 and Section 6.2 and the Parties' respective exclusivity obligations under Section 6.7, (a) each Party shall have the right to Exploit the Joint Collaboration IP without a duty of seeking consent or accounting to the other Party and (b) each Party hereby grants to the other Party a non-exclusive license to such Party's interest in the Joint Collaboration IP for all purposes. Each Party shall, and hereby does, assign, transfer and otherwise convey, and shall cause its Affiliates and its and their Sublicensees to so assign, transfer and otherwise convey, to the other Party, without additional compensation, all such right, title and interest in and to any Joint Collaboration IP as is necessary to fully effect the joint ownership thereof as provided for in this Section 8.1.2.

8.1.3 United States Law. The determination of whether Information and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent Rights, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States irrespective of where such conception, discovery, development or making occurs. To the extent that the Applicable Law in any jurisdiction other than the United States affects the ownership of intellectual property, as a matter of law, in a manner that is inconsistent with the application of Applicable Law in the United States, the Parties shall assign, transfer and otherwise convey, to the other Party, without additional compensation, all such right, title and interest in and to any applicable intellectual property as is necessary to fully effect the ownership thereof as provided for in this Section 8.1.3.

8.1.4 Assignment Obligation. Each Party shall cause all Persons who perform Development activities, Non-Approval Trials, Manufacturing activities or regulatory activities for such Party under this Agreement to be under an obligation to assign their rights in any Information and inventions resulting therefrom to such Party, except (a) if Applicable Law requires otherwise, (b) subject to Section 3.1.5, in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment, or (c) in the case of any Third Party services provider (such as a contract manufacturer or contract research organization), with respect to any Information or inventions that constitute improvements to the background intellectual property of such Third Party, in which case ((a) through (c)), such Party shall use commercially reasonable efforts to obtain a suitable license, or right to obtain such a license, with respect to such Information and inventions, it being understood and agreed that in the case of Third Party contract manufacturers and other service providers it may be commercially reasonable not to obtain a license, [***] Third Party contract manufacturers are set forth in ARTICLE 5.

8.1.5 Control of Product-Specific Know-How and Product-Specific Patents.

(a) Licensor shall ensure that it sufficiently Controls (a) any and all Information first owned or otherwise controlled (through license or otherwise) by Licensor or any of its Affiliates after the Effective Date that would otherwise be Licensor Product-Specific Know-How if Controlled by Licensor and (b) any and all Patent Rights first owned or otherwise controlled (through license or otherwise) by Licensor or any of its Affiliates after the Effective Date that would otherwise be Licensor Product-Specific Patents if Controlled by Licensor, in each case (a) and (b), such that Licensor can grant all rights and licenses to Licensee hereunder with respect to such Information and Patent Rights as Licensor Product-Specific Know-How or Licensor Product-Specific Patents, respectively. Notwithstanding the foregoing, this Section 8.1.5(a) shall not apply to any Information or Patent Rights owned or controlled by an Acquirer or its Affiliates prior to the closing of a Change of Control of Licensor, or to any commitments made by an Acquirer or

its Affiliates prior to such closing with respect to later-developed or later-acquired Information or Patent Rights.

(b) Licensee shall ensure that it sufficiently Controls (a) any and all Information first owned or otherwise controlled (through license or otherwise) by Licensee or any of its Affiliates after the Effective Date that would otherwise be Licensee Product-Specific Know-How if Controlled by Licensee and (b) any and all Patent Rights first owned or otherwise controlled (through license or otherwise) by Licensee or any of its Affiliates after the Effective Date that would otherwise be Licensee Product-Specific Patents if Controlled by Licensee, in each case (a) and (b), such that Licensee can grant all rights and licenses to Licensor hereunder with respect to such Information and Patent Rights as Licensee Product-Specific Know-How or Licensee Product-Specific Patents, respectively. Notwithstanding the foregoing, this Section 8.1.5(b) shall not apply to any Information or Patent Rights owned or controlled by an Acquiror or its Affiliates prior to the closing of a Change of Control of Licensee, or to any commitments made by such Acquiror or its Affiliates prior to such closing with respect to later-developed or later-acquired Information or Patent Rights.

8.2 Prosecution and Maintenance of Patents.

8.2.1 Prosecution and Maintenance of Product-Related Patents.

(a) Prosecution and Maintenance.

[***]

(b) [***]

8.2.2 Prosecution and Maintenance of Licensee Core Technology Patents that are not also Joint Collaboration Patents [or Alnylam Delivery Patents][80]. [***]

8.2.3 Prosecution and Maintenance of Licensor Core Technology Patents that are not also Joint Collaboration Patents [or Alnylam Delivery Patents][81]. [***]

8.2.4 [***]

[80] Note to Draft: Delete this bracketed language if Alnylam is Licensor or the Target is not an Eye Target or CNS Target.

[81] Note to Draft: Delete this bracketed language if Alnylam is Licensee or the Target is not an Eye Target or CNS Target.

8.2.5 Cooperation. The Parties agree to cooperate fully in the preparation, filing, prosecution, and maintenance of the Product-Related Patents and Alnylam Delivery Patents under this Agreement. Cooperation shall include the Parties:

(a) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to (i) enable the other Party to apply for and to prosecute the Product-Related Patents and Alnylam Delivery Patents in the Territory; and (ii) obtain and maintain any Patent Right extensions, supplementary protection certificates, and the like with respect to the Product-Related Patents and Alnylam Delivery Patents, in each case ((i) and (ii)), to the extent provided for in this Agreement; and

(b) promptly informing the other Party of any matters coming to such Party's attention that may materially affect the preparation, filing, prosecution, or maintenance of any such Product-Related Patents and Alnylam Delivery Patents.

8.2.6 Patent Term Extension and Supplementary Protection Certificate. [***]

8.2.7 Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this ARTICLE 8, neither Party shall have the right to make an election under 35 U.S.C. § 102(c) when exercising its rights under this ARTICLE 8 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. § 100(h).

8.2.8 Patent Listings.

[***]

8.3 Enforcement of Patents and Information.

8.3.1 Notices. Each Party shall promptly notify the other Party in writing of any (a) known or suspected infringement of any Licensor Technology or Licensee Technology or (b) unauthorized use or misappropriation of any Confidential Information or Information of a Party by a Third Party of which such Party becomes aware, in each case, to the extent such alleged infringing, unauthorized or misappropriating activities involve, as to any Collaboration Product, a Competing Product with respect thereto in the Field (the "**Competitive Infringement**").

8.3.2 Product-Related IP.

[***]

8.3.3 Licensor Core Technology Patents and Licensor Core Technology Know-How that are not also Joint Collaboration IP [or Alnylam Delivery Patents][82]. [***]

8.3.4 Licensee Core Technology Patents and Licensee Core Technology Know-How that are not also Joint Collaboration IP [or Alnylam Delivery Patents][83]. [***]

8.3.5 Generic Competition. Notwithstanding the foregoing, if either Party (a) reasonably believes that a Third Party may be filing or preparing or seeking to file a generic or abridged Drug Approval Application that refers or relies on Regulatory Documentation submitted by either Party to any Regulatory Authority, whether or not such filing may infringe the Product-Related Patents or Alnylam Delivery Patents; (b) receives any notice of certification regarding any Product-Related Patent or Alnylam Delivery Patent pursuant to the U.S. "Drug Price Competition and Patent Term Restoration Act" of 1984 (21 United States Code § 355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)) ("**ANDA Act**") claiming that any such Patent Rights are invalid or unenforceable or claiming that any such Patent Rights will not be infringed by the Manufacture, use, marketing or sale of a product for which an application under the ANDA Act is filed; or (c) receives any equivalent or similar certification or notice in any other jurisdiction, in each case ((a) through (c)), it shall (i) notify the other Party in writing identifying the alleged applicant or potential applicant and furnishing the information upon which determination is based and (ii) provide such other Party with a copy of any such notice of certification within ten (10) days of the date of receipt, and the Parties' rights and obligations with respect to any legal action as a result of such certification shall be as set forth in Section 8.3.2 and Section 8.3.6.

8.3.6 Cooperation and Settlement. The Parties agree to cooperate fully in any Infringement Action pursuant to this Section 8.3. If a Party brings such an Infringement Action, the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any Infringement Action in accordance with this Section 8.3 shall have the right to settle such claim without the other Party's consent; provided, however, that such Party shall not have the right to settle such Infringement Action in a manner that involves an admission of invalidity or unenforceability with respect to Patent Rights Controlled by such other Party (including Joint Collaboration Patents), without the prior consent of the other Party, such consent to be granted or withheld in its sole discretion. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court.

[82] Note to Draft: Delete this bracketed language if Alnylam is Licensee or the Target is not an Eye Target or CNS Target.

[83] Note to Draft: Delete this bracketed language if Alnylam is Licensor or the Target is not an Eye Target or CNS Target.

8.3.7 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of an Infringement Action described in Section 8.3.2, Section 8.3.3, Section 8.3.4 and Section 8.3.5 (whether by way of settlement or otherwise) with respect to a Competitive Infringement shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be:

(a) if Licensee controlled such Infringement Action, retained by such Licensee; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales or profit with respect to a Collaboration Product, then Licensor shall receive [***] of such attributable amount of such award or settlement; or

(b) if Licensor controlled such Infringement Action, [***] to Licensor and [***] to Licensee.

8.4 Administrative Proceedings.

8.4.1 Each Party shall promptly notify the other Party in writing upon receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, post-grant review, inter partes review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to any of the Product-Related Patents or Alnylam Delivery Patents. The Parties shall thereafter consult and reasonably cooperate to determine a course of action with respect to any such proceeding and shall reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms; provided, however, that, except as otherwise agreed by the Parties, and except as set forth below in Section 8.4.2, the Party that has the right to prosecute such Product-Related Patent or Alnylam Delivery Patent, as applicable, shall control and have final decision-making authority with respect to any such proceeding relating to such Product-Related Patent or Alnylam Delivery Patent, as applicable.

8.4.2 If any proceeding under Section 8.4.1 involves Patent Rights involved in an Infringement Action under Section 8.3.2, Section 8.3.3, Section 8.3.4 or Section 8.3.5, or an invalidity or unenforceability action under Section 8.5, any decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, shall be made by the Party controlling such Infringement Action or such invalidity or unenforceability action.

8.4.3 All costs and expenses incurred in connection with any proceeding under this Section 8.4 will be borne in the same manner as costs and expenses incurred with respect to prosecution and maintenance of such Patent Rights pursuant to Section 8.2.

8.5 Invalidity or Unenforceability Defenses or Actions.

8.5.1 Notices. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability (except as made in an administrative proceeding under Section 8.4) of any of the Product-Related Patents or Alnylam Delivery Patents by a Third Party, including in a declaratory judgment action or similar action or claim filed by a Third Party or as a defense or as a counterclaim in any Infringement Action with respect to a Competitive Infringement initiated pursuant to Section 8.3.2, Section 8.3.3, Section 8.3.4 or Section 8.3.5, in each case, of which such Party becomes aware.

8.5.2 Product-Related Patents [and Alnylam Delivery Patents][84]. [***]

8.5.3 Licensor Core Technology Patents that are not also Joint Collaboration Patents [or Alnylam Delivery Patents][85]. Licensor shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensor Core Technology Patents that are not also Joint Collaboration Patents [or Alnylam Delivery Patents][86] at its own cost and expense.

8.5.4 Licensee Core Technology Patents that are not also Joint Collaboration Patents [or Alnylam Delivery Patents][87]. Licensee shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensee Core Technology Patents that are not also Joint Collaboration Patents [or Alnylam Delivery Patents][88] at its own cost and expense.

[84] Note to Draft: Delete this bracketed language if the Target is not an Eye Target or CNS Target.
[85] Note to Draft: Delete this bracketed language if Alnylam is Licensee or the Target is not an Eye Target or CNS Target.
[86] Note to Draft: Delete this bracketed language if Alnylam is Licensee or the Target is not an Eye Target or CNS Target.
[87] Note to Draft: Delete this bracketed language if Alnylam is Licensor or the Target is not an Eye Target or CNS Target.
[88] Note to Draft: Delete this bracketed language if Alnylam is Licensor or the Target is not an Eye Target or CNS Target.

8.5.5 Cooperation. With respect to Product-Related Patents and Alnylam Delivery Patents, each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 8.5, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party shall keep the other Party reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim, or counterclaim; provided, however, the foregoing consultation obligation will be limited to only those Product-Related Patents and Alnylam Delivery Patents Controlled by the other Party. In connection with the activities set forth in this Section 8.5, the controlling Party shall consider in good faith any comments from the other Party, and each Party shall consult with the other as to the strategy for the defense of the Product-Related Patents and Alnylam Delivery Patents; provided, however, the foregoing consultation obligation will be limited to only those Patent Rights Controlled by the other Party.

8.5.6 Costs and Expenses. The defending Party shall bear all costs and expenses (other than the costs and expenses of the non-controlling Party's participation in any claim, suit or proceeding in the Territory with independent counsel of such Party's choice as provided in Section 8.5.2) incurred in defending a claim, suit or proceeding under Section 8.5.2 with respect to Product-Related Patents, and if the defending Party is Licensee, Licensee may offset up to [***] of such costs and expenses in a given Calendar Quarter incurred in defending a claim, suit or proceeding under Section 8.5.2 with respect to Product-Related Patents against any amounts otherwise owed to Licensor under this Agreement for such Calendar Quarter subject to Section 7.1.5(c).

8.6 Infringement Claims by Third Parties.

8.6.1 Notices. If the Development, Manufacture or Commercialization of a Collaboration Product in the Field pursuant to this Agreement results in, or may result in, an infringement action by a Third Party alleging infringement of such Third Party's intellectual property (a "**Third Party Infringement Action**"), the Party first receiving notice thereof shall promptly notify the other Party thereof in writing.

8.6.2 Defense. [***]

8.6.3 Settlement. [***]

8.6.4 Costs and Expenses; Recovery. [***]

8.7 Product Trademarks and Domain Names.

8.7.1 Ownership and Prosecution of Product Trademarks and Domain Names. Licensee shall own all right, title, and interest to the Product Trademarks and Domain Names in the Territory, and shall be responsible for the registration, prosecution, maintenance, enforcement and defense thereof. Licensee shall bear the Out-of-Pocket Costs (other than the costs and expenses of Licensor's participation in any claim, suit or proceeding with respect to the Product Trademarks and Domain Names with independent counsel of such Party's choice) incurred with respect to the Product Trademarks and Domain Names. Licensor shall provide all assistance and documents reasonably requested by Licensee in support of its prosecution, registration, maintenance, enforcement and defense of the Product Trademarks and Domain Names.

8.7.2 Ownership of Corporate Names. As between the Parties, each Party shall retain all right, title and interest in and to its respective Corporate Names.

8.8 Discussion of Potential Material Intellectual Property Issues. Each Party's legal/intellectual property department shall keep the other Party's legal/intellectual property department reasonably apprised of any potential material Patent Right or other intellectual property-related issue with respect to activities under this Agreement, which may be made pursuant to a mutually acceptable and customary common interest agreement entered into by the Parties; provided that the foregoing shall not impose any duty on either Party to conduct or obtain freedom-to-operate or validity or similar opinions of counsel or Patent Right or other intellectual property clearance searches to the extent not already conducted or obtained by such Party.

8.9 Intellectual Property that Relates to Multiple Programs. [***]

8.10 [**Transition of Patent Matters**. Upon Licensee's request, subject to Section 8.2.1(b), Licensor shall use commercially reasonable efforts to promptly provide Licensee with the appropriate documents for the transfer of responsibility and control of preparation, filing, prosecution, and maintenance of the Product-Related Patents in the Territory and reasonably cooperate with Licensee with respect to such transfer, including executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to (a) enable Licensee to apply for and to prosecute, maintain, defend and enforce the Product-Related Patents in the Territory, and (b) obtain and maintain any Patent Right extensions, supplementary protection certificates, and the like with respect to the Product-Related Patents, in each case ((a) and (b)), to the extent provided for in this Agreement. Licensor shall promptly inform Licensee of any matters coming to Licensor's attention that may materially affect the preparation, filing, prosecution, or maintenance of any such Product-Related Patents.][89]

[89] Note to Draft: Delete this Section 8.10 if Alnylam is Licensee.

Article 9
CONFIDENTIALITY AND NON-DISCLOSURE

9.1 Confidentiality Obligations. At all times during the Term and for a period of [***] years following termination or expiration hereof in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is necessary or reasonably useful for the performance of, or the exercise of such Party's rights under, this Agreement. "**Confidential Information**" means any technical, business, or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information of Third Parties, information relating to the terms of this Agreement, any Collaboration Product (including the Regulatory Documentation and Development Data), any Development or Commercialization of any Collaboration Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Licensee Know-How (which shall be the Confidential Information of Licensee) and Licensor Know-How (which shall be the Confidential Information of Licensor), as applicable), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, during the Term, (a) all Regulatory Documentation owned by Licensee pursuant to Section 3.4.1(b) ("**Product Regulatory Documentation**") shall be deemed to be the Confidential Information of Licensee, and Licensee shall be deemed to be the disclosing Party and Licensor shall be deemed to be the receiving Party with respect thereto, (b) all Information Controlled by a Party that is specifically and solely related to Product-Specific Factors ("**Product-Specific Information**") shall be deemed to be the Confidential Information of Licensee, and Licensee shall be deemed to be the receiving Party and Licensor shall be deemed to be the disclosing Party with respect thereto, [***]. For purposes of this Agreement, all confidential information related to the Target Program or any Collaboration Products disclosed by a Party under the terms of the Master Agreement is hereby deemed to be the Confidential Information of such Party and will be treated as if disclosed hereunder and subject to the terms of this Agreement; provided that Product Regulatory Documentation, Product-Specific Information and Joint Collaboration IP shall be subject to the immediately preceding sentence, even if disclosed under the terms of the Master Agreement. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 9.1 with respect to any Confidential Information shall not include any information that:

9.1.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party or any of its Affiliates or any Person to whom the receiving Party provided such information;

9.1.2 can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality to the disclosing Party with respect to such information; provided that the foregoing exception shall not apply with respect to Product Regulatory Documentation, Product-Specific Information or Joint Collaboration IP;

9.1.3 is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality to the disclosing Party with respect to such information; or

9.1.4 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; provided that the foregoing exception shall not apply with respect to Product Regulatory Documentation, Product-Specific Information or Joint Collaboration IP.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

9.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

9.2.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; provided, however, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order or required to be disclosed be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by Applicable Law; and provided further that the Confidential Information disclosed in response to such court or governmental order or as required by Applicable Law shall be limited to that information which is legally required to be disclosed in response to such court or governmental order or by such Applicable Law;

9.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for INDs or Regulatory Approval pursuant to the terms of this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

9.2.3 made by the receiving Party or its Affiliates or Sublicensees to its or their attorneys, auditors, advisors, consultants, contractors, existing or prospective collaboration partners, licensees, sublicensees, or acquirers as may be necessary or reasonably useful in connection with, or to its or their existing or prospective investors, lenders or financing partners as may be necessary in connection with, the Exploitation of any Collaboration Product, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement, or to potential or actual investors, lenders, financing partners, collaboration partners, licensees, sublicensees, or acquirers as may be necessary or reasonably useful in connection with their evaluation of such potential or actual transaction; provided, however, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this ARTICLE 9 (but with respect to disclosing the terms of this Agreement to existing or prospective non-strategic financial investors, lenders or financing partners, then with a duration of confidentiality as appropriate that is no less than [***] years from the date of disclosure);

9.2.4 with respect to Joint Collaboration IP made by either Party or its Affiliates as may be necessary or reasonably useful in connection with the Exploitation of any product so long as such Party or its Affiliates is not in violation of this Agreement, including under Section 6.1, Section 6.2 and Section 6.7; or

9.2.5 required under an In-License; provided that the recipient is subject in writing to substantially the same confidentiality obligations as the Parties.

9.3 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 9.3 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

9.4 Public Announcements. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party’s prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party’s counsel, required by Applicable Law or the rules of a stock exchange on which

the securities of the disclosing Party are listed (or to which an application for listing has been submitted) and except that a Party may, once a press release or other public written statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other public written statement without the further approval of the other Party. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Notwithstanding the foregoing, Licensee, its Affiliates and its and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding any Collaboration Product; provided (a) such disclosure is subject to the provisions of this ARTICLE 9 with respect to Licensor's Confidential Information and (b) Licensee shall not use the name of Licensor (or insignia, or any contraction, abbreviation or adaptation thereof) without Licensor's prior written permission. Notwithstanding the foregoing, Licensee will consider in good faith any request by Licensor to issue a joint press release or public disclosure with Licensor to the extent that such disclosure describes the commencement or "top-line" results of Clinical Trials of a Collaboration Product, the achievement of any material Development events with respect to a Collaboration Product or the filing for or receipt of Regulatory Approval with respect to the Collaboration Product in the Territory. Prior to making any public disclosure, to the extent practicable, Licensee shall provide Licensor with a draft of such proposed disclosure for Licensor's review and comment, which shall be considered in good faith by Licensee. Such draft shall be provided to Licensor at least [***] day (or, to the extent faster timely disclosure of a material event is required by Applicable Law or stock exchange or stock market rules, such shorter period of time sufficiently in advance of the disclosure so that Licensor will have the opportunity to comment upon the disclosure and Licensee will be able to comply with its obligations as required by Applicable Law or stock exchange or stock market rules) prior to making any such disclosure, for Licensor's review and comment, which shall be considered in good faith by Licensee. Without limiting the foregoing, the Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party shall be entitled to make such filings, except that the Parties shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with Applicable Law. The filing Party shall provide the non-filing Party with an advance copy of this Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider the non-filing Party's timely comments thereon and cooperate with such non-filing Party in seeking such confidential treatment and, upon the written request of the non-filing Party, shall request an appropriate extension of the term of the confidential

treatment period. For the avoidance of doubt, each Party shall be responsible for its own legal and other costs in connection with any filing governed by the terms of this Section 9.4.

9.5 Publications. As between the Parties, Licensee shall have the sole right, in consultation with Licensor, to issue and control all publications in scientific journals and make scientific presentations related to any Collaboration Product. Licensee shall provide Licensor with an advance copy of the proposed publication, and Licensor shall then have [***] days prior to submission for any publication in which to comment and to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Information belonging in whole or in part to Licensor or that is the Confidential Information of Licensor. If Licensor informs Licensee that such publication, in Licensor's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to Licensor, or on any Information that is Confidential Information of Licensor, Licensee shall delay or prevent such publication as follows: (i) with respect to a patentable invention, such publication shall be delayed sufficiently long (not to exceed [***] days) to permit the timely preparation and filing of a patent application; and (ii) with respect to Information that is Confidential Information of such Licensor (other than the results of a Clinical Trial or any Product Regulatory Information), such Information shall be deleted from the publication. Licensee will also consider in good faith any other comments of Licensor. Any publication shall include recognition of the contributions of Licensor according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

9.6 Return of Confidential Information. Upon the effective date of the expiration pursuant to Section 12.1 or termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which such other Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, however, the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 9.1.

9.7 Confidential Information that Relates to Multiple Programs. Notwithstanding the foregoing provisions of this ARTICLE 9, if (a) there is Confidential Information of a Party

hereunder that is also Confidential Information of such Party under the Master Agreement, a Co-Co Collaboration Agreement or another License Agreement (as "Confidential Information" is defined in such other agreement), and (b) there is a conflict between the provisions of this Agreement, on the one hand, and the Master Agreement, a Co-Co Collaboration Agreement or License Agreement, as applicable, on the other hand, with respect to the disclosure and non-use of such Confidential Information, the provisions of the agreement that provides the most protection of a Party's Confidential Information (i.e., Licensee, with respect to Licensee's Confidential Information, and Licensor, with respect to Licensor's Confidential Information) shall control.

Article 10
REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Licensor and Licensee each represents and warrants to the other, as of the Effective Date, as follows:

10.1.1 Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

10.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party (or any of its Affiliates) is bound, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party (or any of its Affiliates).

10.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

10.1.4 No Debarment. Neither it nor any of its Affiliates, nor its or their respective employees, have been debarred or are subject to debarment.

10.1.5 No Inconsistent Obligation. It (and each of its Affiliates) is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

10.1.6 Governmental Consents. Except as set forth in Section 4.9 of the Master Agreement, no authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or will be necessary to be obtained by such Party for, or in connection with, the transaction contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as set forth in Section 3.4.

10.1.7 Third Party Consents. Except as set forth in Section 4.9 of the Master Agreement, it has obtained all necessary authorizations, consents and approvals of any Third Party that is required to be obtained by it as of the Effective Date for, or in connection with, the transaction contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as set forth in Section 3.4.

10.2 [90][**Additional Representations, Warranties and Covenants of Licensor.** Except as provided in **Schedule 10.2**, Licensor further represents and warrants to Licensee, as of the Effective Date, and covenants, as follows:

10.2.1 Licensor is the sole and exclusive owner of, or otherwise Controls pursuant to an Existing Licensor In-License (or will Control pursuant to an Additional Alnylam In-License at such time that such Additional Alnylam In-License is included as an Existing Licensor In-License pursuant to Section 6.5.2), the Licensor Background Technology, and all of the Licensor Background Technology licensed to Licensee hereunder that is solely and exclusively owned by Licensor is free and clear of liens, charges or encumbrances other than licenses and rights granted to Third Parties that are not inconsistent with the rights and licenses granted to Licensee under this Agreement.

10.2.2 Licensor has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Licensor Background Technology to grant the licenses to such Licensor Background Technology granted to Licensee pursuant to this Agreement.

10.2.3 [***]

10.2.4 All Licensor Patents for which Licensor or any of its Affiliates controls prosecution and maintenance (the "**Licensor Managed Patents**") are filed and maintained properly and correctly and, to Licensor's Knowledge, all applicable fees have been paid on or before any final due date for payment. Licensor has complied with all Applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Licensor Managed Patents.

[90] Note to Draft: If Regeneron is Licensor, then the following Section 10.2 should be replaced with alternative Section 10.2 below.

10.2.5 To Licensor's Knowledge, the Licensor Patents are, or, upon issuance, will be, valid and enforceable Patent Rights.

10.2.6 [***]

10.2.7 [***]

10.2.8 Licensor has obtained from all inventors of Licensor Background Technology that is indicated on **Schedule 1.128** or **Schedule 1.135** as being solely and exclusively owned by Licensor or any of its Affiliates valid and enforceable agreements that have assigned to Licensor or its Affiliate each such inventor's entire right, title and interest in and to all such Licensor Background Technology.

10.2.9 To Licensor's Knowledge, the Exploitation of the Licensor Background Technology with respect to the Collaboration Products as contemplated under this Agreement, (a) does not and will not infringe any issued Patent Right of any Third Party or misappropriate any Information or other intellectual property of any Third Party and (b) will not infringe the claims of any published Third Party patent application when and if such claims were to issue in their current form.

10.2.10 [***]

10.2.11 **Schedule 1.69** sets forth a complete and accurate list of all agreements between Licensor and a Third Party entered into prior to the Effective Date pursuant to which Licensor Controls (or will Control pursuant to an Additional Alnylam In-License at such time that such Additional Alnylam In-License is included as an Existing Licensor In-License pursuant to Section 6.5.2) Information or Patent Rights that are necessary or reasonably useful to the practice of the Licensor Background Technology as contemplated in this Agreement. Licensor has provided Licensee with true and complete copies of all Existing Licensor In-Licenses and all Additional Alnylam In-Licenses. [***]

10.2.12 [***]

10.2.13 Part 1 of **Schedule 10.2.13** sets forth a true, correct and complete list of [***]. Part 2 of **Schedule 10.2.13** sets forth a true, correct and complete description of all terms and conditions [***].

[ALTERNATIVE SECTION 10.2] [**Additional Representations and Warranties of Licensor.** Except as provided in **Schedule 10.2**, Licensor further represents and warrants to Licensee, as of the Effective Date, as follows:

10.2.1 Neither Licensor nor any of its Affiliates has granted any Third Party, and neither Licensor nor any of its Affiliates is under any obligation to grant any Third Party, any right to Exploit any Collaboration Product in the Territory, except as set forth in Section 6.7.3.

10.2.2 To Licensor's Knowledge, **Schedule 1.135** sets forth a complete and accurate list of the Licensor Product-Specific Patents. Licensor or one of its Affiliates is the sole and exclusive owner of all Licensor Product-Specific Patents identified on **Schedule 1.135**. Licensor has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Licensor Product-Specific Patents and Licensor Product-Specific Know-How within the Licensor Background Technology to grant the licenses to such Licensor Product-Specific Patents and Licensor Product-Specific Know-How granted to Licensee pursuant to this Agreement.

10.2.3 All Licensor Product-Specific Patents for which Licensor or any of its Affiliates controls prosecution and maintenance (the "**Licensor Managed Patents**") are filed and maintained properly and correctly and, to Licensor's Knowledge, all applicable fees have been paid on or before any final due date for payment. Licensor has complied with all Applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Licensor Managed Patents.

10.2.4 To Licensor's Knowledge, the Licensor Product-Specific Patents are, or, upon issuance, will be, valid and enforceable Patent Rights.

10.2.5 Neither Licensor nor any of its Affiliates has granted any Third Party, and neither Licensor nor any of its Affiliates is under any obligation to grant any Third Party any rights under Licensor Product-Specific Know-How or Licensor Product-Specific Patents or otherwise assign to any Third Party any Information or Patent Rights that would otherwise constitute Licensor Product-Specific Know-How or Licensor Product-Specific Patents.

10.2.6 Licensor has obtained from all inventors of Licensor Product-Specific Patents within the Licensor Background Technology that is indicated on **Schedule 1.135** as being solely and exclusively owned by Licensor or any of its Affiliates valid and enforceable agreements that have assigned to Licensor or its Affiliate each such inventor's entire right, title and interest in and to all such Licensor Product-Specific Patents within the Licensor Background Technology.

10.2.7 [***]

10.2.8 Licensor has provided Licensee with true and complete copies of all Existing Licensor In-Licenses (subject to any applicable confidentiality restrictions). There are no terms or conditions in any Existing Licensor In-License or Existing Licensor Third Party Agreement that (a) would prevent Licensee from exercising its rights under this Agreement with respect to the prosecution, maintenance, enforcement or defense of any Product-Related IP; (b) would require

Licensor or any of its Affiliates to grant any Third Party rights under Licensor Product-Specific Know-How or Licensor Product-Specific Patents or (c) grant to any Third Party contractual exclusivity with respect to the development, manufacture or commercialization of an siRNA Directed to the Target. Neither Licensor nor its Affiliates are in material breach or default under any Existing Licensor In-License, nor, to Licensor's Knowledge, is any counterparty thereto in material breach of any Existing Licensor In-License, and neither Licensor nor its Affiliates have received any written notice of breach or default with respect to any Existing Licensor In-License. The licenses granted to Licensor or its Affiliates in the Existing Licensor In-Licenses are in full force and effect and, subject to their terms, are sublicenseable to Licensee as contemplated by this Agreement. The execution and performance of this Agreement does not constitute a material breach of any Existing Licensor In-License.

10.2.9 **Schedule 10.2.9** sets forth a true, correct and complete list of all [***].][91]

10.3 **Additional Representations, Warranties and Covenants of Licensee.** Except as provided in **Schedule 10.3**, Licensee further represents and warrants to Licensor, as of the Effective Date, as follows:

10.3.1 Neither Licensee nor any of its Affiliates has granted any Third Party, and neither Licensee nor any of its Affiliates is under any obligation to grant any Third Party, any right to Exploit any Collaboration Product in the Territory[, except as set forth in Section 6.7.3][92].

10.4 **DISCLAIMER OF WARRANTIES.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENT RIGHTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. FOR THE AVOIDANCE OF DOUBT, THE FOREGOING IS NOT INTENDED TO LIMIT IN ANY WAY ANY EXPRESS REPRESENTATIONS OR WARRANTIES MADE BY EITHER PARTY UNDER THE MASTER AGREEMENT, ANY OTHER LICENSE AGREEMENT OR ANY CO-CO COLLABORATION AGREEMENT.

[91] Note to Draft: If Regeneron is Licensor, then use this alternative Section 10.2.

[92] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

10.5 Additional Covenants.

10.5.1 Compliance. Each Party and its Affiliates and Sublicensees shall conduct the Development, Manufacture and Commercialization of the Collaboration Products in material accordance with all Applicable Laws and industry standards, including, to the extent applicable, current governmental regulations concerning good laboratory practices, good clinical practices and good manufacturing practices. Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

10.5.2 Debarment. Neither Party nor any of its Affiliates will use in any capacity, in connection with the performance of its obligations under this Agreement, any Person that has been debarred. Each Party agrees to inform the other Party in writing promptly if it learns that it or any Person that is performing activities in connection with activities under this Agreement is debarred or is subject to debarment, or, to the notifying Party's Knowledge, if debarment of the notifying Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the performance of its obligations under this Agreement, is threatened.

Article 11
INDEMNITY

11.1 Indemnity.

11.1.1 Licensor's Indemnification Obligations. Licensor shall defend, indemnify and hold harmless Licensee, its Affiliates and its and their respective officers, directors, employees and agents ("**Licensee Indemnitees**") from and against all loss, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs payable to a Third Party (collectively, "**Damages**"), incurred by any Licensee Indemnitee as a result of a Third Party's claim, action, suit, settlement, or proceeding (each, a "**Claim**") against a Licensee Indemnitee to the extent such Claim arises out of or results from:

(a) the gross negligence, recklessness, willful misconduct, or intentional wrongful acts or omissions of Licensor or any of its Affiliates (or its or their respective agents, contractors, Sublicensees, partners, representatives or other Persons working on its or their behalf) in its or their respective performance under this Agreement[, the Supply Agreement (if any) or the Quality Agreement (if any), including (i) the Manufacture and supply of (A) the Early

Stage Supply Requirements and (B) if applicable, Late Stage Supply Requirements and (ii) Licensor's performance of Alnylam Specific Activities][93]; or

(b) a breach by Licensor of this Agreement (including the inaccuracy of any representation or warranty made by Licensor in this Agreement)[, the Supply Agreement (if any) or the Quality Agreement (if any)][94]; or

(c) any amounts payable to a Third Party under a Licensor In-License based on a sharing with such Third Party of (i) amounts paid to Licensor by Licensee pursuant to this Agreement or (ii) any Third Party Transaction Proceeds (e.g., any amounts payable to a Third Party that constitute a share of any sublicensing income); or

(d) [the Excluded Agreements or any of the intellectual property licensed thereunder (including infringement or misappropriation thereof) with respect to activities hereunder;][95]

except, in the case of (a) and (b), for those Damages for which Licensee has an obligation to indemnify Licensor pursuant to Section 11.1.2(a) or Section 11.1.2(b), as to which Damages each Party shall indemnify the other Party and the Licensee Indemnitees or Licensor Indemnitees, as applicable, to the extent of its respective liability for such Damages.

11.1.2 Licensee's Indemnification Obligations. Licensee shall defend, indemnify and hold harmless Licensor, its Affiliates and its and their respective officers, directors, employees and agents ("**Licensor Indemnitees**") from and against all Damages incurred by any Licensor Indemnitee as a result of a Claim against a Licensor Indemnitee to the extent such Claim arises out of or results from:

(a) the gross negligence, recklessness, willful misconduct, or intentional wrongful acts or omissions of Licensee or any of its Affiliates (or its or their respective agents, contractors, Sublicensees, partners, representatives or other Persons working on its or their behalf) in its or their respective performance under this Agreement, including in connection with the Exploitation of any Collaboration Product by or on behalf of Licensee;

(b) a breach by Licensee of this Agreement (including the inaccuracy of any representation or warranty made by Licensee in this Agreement);

[93] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[94] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[95] Note to Draft: Delete this bracketed language if Regeneron is Licensor.

(c) the Exploitation of any Collaboration Product by or on behalf of Licensee pursuant to this Agreement; or

(d) any amounts payable to a Third Party under a Licensee In-License based on a sharing with such Third Party of (i) amounts paid to Licensee by Licensor pursuant to this Agreement or (ii) any Third Party Transaction Proceeds (e.g., any amounts payable to a Third Party that constitute a share of any sublicensing income); or

(e) [the Excluded Agreements or any of the intellectual property licensed thereunder (including infringement or misappropriation thereof) with respect to activities hereunder;][96]

except, in the case (a), (b) and (c), for those Damages for which Licensor has an obligation to indemnify Licensee pursuant to Section 11.1.1(a) or Section 11.1.1(b), as to which Damages each Party shall indemnify the other Party and the Licensee Indemnitees or Licensor Indemnitees, as applicable, to the extent of its respective liability for such Damages.

11.2 Indemnity Procedure.

11.2.1 Notification. The Party entitled to indemnification under Section 11.1.1 or Section 11.1.2 (an "**Indemnified Party**") shall notify the Party potentially responsible for such indemnification (the "**Indemnifying Party**") within five (5) Business Days of becoming aware of any Claim asserted or threatened in writing against the Indemnified Party that could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that such failure materially prejudices the Indemnifying Party.

[96] Note to Draft: Delete this bracketed language if Regeneron is Licensee.

11.2.2 Control of Defense. If the Indemnifying Party elects in writing to the Indemnified Party that it will assume control of the defense of such Claim, the Indemnifying Party shall have the right to defend such Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless the Indemnified Party consents to such compromise or settlement, which consent shall not be unreasonably withheld, conditioned or delayed, and which consent shall be deemed given with respect to any Damages relating solely to the payment of money damages if such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim. If the Indemnifying Party does not elect to assume control of the defense of such Claim within forty-five (45) days of its receipt of notice thereof, or if the Indemnifying Party elects in writing to the Indemnified Party to cease maintaining control of the defense of such Claim, the Indemnified Party shall have the right upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such Claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such Claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such Claim. The Indemnified Party may not compromise or settle such Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

11.2.3 Indemnified Party's Participation. The Indemnified Party shall cooperate with the Indemnifying Party in, and may participate in, but not control, any defense or settlement of any Claim controlled by the Indemnifying Party pursuant to this Section 11.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that, if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party, on the one hand, and the Indemnified Party and Licensor Indemnitees or Licensee Indemnitees, as applicable, on the other hand, the Indemnifying Party shall bear such costs and expenses.

11.2.4 Expenses. With respect to Claims under Section 11.1.1 or Section 11.1.2, the costs and expenses, including fees and disbursements of counsel, (a) incurred by the Indemnifying Party, shall be the responsibility of the Indemnifying Party or (b) incurred by the Indemnified Party pursuant to the proviso in Section 11.2.3 shall be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to

contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party or the Licensor Indemnitees or Licensee Indemnitees, as applicable.

11.3 Insurance. During the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by Applicable Law, each of Licensor and Licensee shall (a) use Commercially Reasonable Efforts to procure and maintain appropriate commercial general liability and product liability insurance in an [***] or (b) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Licensee or Licensor, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Section 11.1 or otherwise. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party.

Article 12
TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the last Royalty Term for the last Collaboration Product (such period, the "**Term**").

12.2 Termination for Material Breach. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") has materially breached this Agreement[, the Supply Agreement (if any) or the Quality Agreement (if any)][97] in a manner that fundamentally frustrates the value or essential characteristics of the transactions contemplated by this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "**Default Notice**"). If the Breaching Party does not dispute that it has committed such a material breach under this Agreement[, the Supply Agreement (if any) or the Quality Agreement (if any)][98] that results in the Non-Breaching Party having a right to terminate this Agreement, then if the Breaching Party fails to cure such breach, or fails to take steps as would be considered reasonable to effectively cure such breach, within ninety (90) days after receipt of the Default Notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party disputes that it has committed a material breach under this Agreement[, the Supply Agreement (if any) or the Quality Agreement (if any)][99] that results in the Non-Breaching Party having a right to terminate this Agreement, the dispute shall be resolved pursuant to Section 13.5. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to have materially breached in a manner that fundamentally frustrates the value or essential characteristics of the transactions contemplated by this Agreement (an "**Adverse Ruling**"), then if the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within ninety (90) days after such ruling, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; provided that if such compliance cannot be fully achieved within such ninety (90)-day cure period, then such cure period will be extended for a period of up to sixty (60) additional days (for a total cure period of one hundred fifty (150) days) if the Breaching Party prepares and provides to the Non-Breaching Party a reasonable written plan for curing such material breach and uses commercially reasonable efforts to cure such material breach in accordance with such written plan, and if such material breach is not cured within such one hundred fifty (150)-day period, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

[97] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[98] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[99] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

12.3 Termination for Insolvency. In the event that either Party (or its ultimate parent) (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within sixty (60) days of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

12.4 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Licensee or Licensor are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

12.5 Licensee Voluntary Termination Right. Licensee may terminate this Agreement at will, in its sole discretion, in its entirety upon ninety (90) days' prior written notice to Licensor at any time.

12.6 Effects of Termination.

12.6.1 Voluntary Termination by Licensee. In the event of a termination of this Agreement in its entirety by Licensee pursuant to Section 12.5, the provisions of **Schedule 12.6.1** shall apply unless Licensor notifies Licensee in writing prior to the effective date of termination

that Licensor desires for the provisions of **Schedule 12.6.2** to apply, in which case, the provisions of **Schedule 12.6.2** shall apply.

12.6.2 Termination by Either Party for Cause. In the event of a termination of this Agreement in its entirety by either Party pursuant to Section 12.2 or Section 12.3, the provisions of **Schedule 12.6.2** shall apply unless (a) the terminating Party is Licensee and Licensee notifies Licensor in writing prior to the effective date of termination that Licensee desires for the provisions of **Schedule 12.6.1** to apply or (b) Licensor notifies Licensee in writing prior to the effective date of termination that Licensor desires for the provisions of **Schedule 12.6.1** to apply, in which case ((a) or (b)), the provisions of **Schedule 12.6.1** shall apply.

12.7 Remedies. Except as otherwise expressly provided herein, expiration or termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

12.8 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued (or that may accrue as a result of activities under this Agreement) to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated or by their nature are intended to survive the termination or expiration of this Agreement, including this Section 12.8, 3.3.1 (for the period set forth therein), 3.3.4, 3.4.2 (last sentence only), 6.1.1 (with respect to any perpetual license following the Royalty Term set forth in Section 6.1.1), 6.1.2 (with respect to any perpetual license following the Royalty Term set forth in Section 6.1.2), 6.1.5 (including the last paragraph of Section 6.1 (i.e., unnumbered paragraph beginning with "Notwithstanding") as applied to Sections 6.1.1, 6.1.2 and 6.1.5 only), 6.2.1 (including the last paragraph of Section 6.2 (i.e., unnumbered paragraph beginning with "Notwithstanding") as applied to Section 6.2.1 only), 6.4, 6.6, 7.1 through 7.3 (to the extent such payments have accrued but not been paid), 7.8, 7.9, 7.10, 7.11, 7.12 (for the period set forth therein), 7.13 (for the three (3)-year period following expiration or termination of this Agreement), 7.14, 8.1.1, 8.1.2, 8.1.3, 8.2.7, 8.7.2, 9.1 (for the period set forth therein), 9.2 (for the period set forth in Section 9.1), 9.3, 9.6, 10.4, 12.4, 12.6 (including, for clarity, **Schedule 12.6.1** and **Schedule 12.6.2**, as applicable) and 12.7; ARTICLES 1 (to the extent necessary to interpret the remaining surviving provisions, and including, for clarity, the corresponding schedules, as applicable), 11 and 13; and **Schedule 1** and **Schedule 2** of this Agreement shall survive the termination or expiration of this Agreement for any reason.[100]

[100] Note to Draft: Survival sections to be updated based on which provisions are ultimately included in the Agreement.

Article 13
MISCELLANEOUS

13.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within seven (7) Business Days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

13.2 Assignment. Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party may make such an assignment without the other Party's consent to its Affiliate or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all of such Party's business, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. With respect to an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section 13.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Licensor or Licensee, as the case may be. In the event either Party seeks and obtains the other Party's consent to assign or delegate its rights or obligations to another Party, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

13.3 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be

fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

13.4 Governing Law, Jurisdiction and Service.

13.4.1 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Except for (a) Financial Disputes, which are governed by Section 13.5, (b) Expedited Matters, which are governed by **Schedule 1**, or (c) Expert Disputes, which are governed by **Schedule 2**, each Party acknowledges and agrees that it must commence any action, suit or proceeding arising out of or in connection with this Agreement (other than appeals therefrom) in the jurisdiction where the other Party is incorporated or has its principal place of business, and each Party hereby waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in courts in such jurisdiction. The Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, with respect to any Legal Dispute, subject, however, to this Section 13.4.1 and Section 13.9.

13.4.2 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 13.6.2 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

13.5 Dispute Resolution.

13.5.1 Except as provided in Section 13.9, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, including Financial Disputes, Expedited Matters, Legal Disputes and Expert Disputes, it shall be resolved pursuant to this Section 13.5.

13.5.2 Either Party may require that any dispute, other than Expedited Matters (which are governed by **Schedule 1** and are referred to Executive Officers pursuant to the terms thereof) and Expert Disputes (which are governed by **Schedule 2**), be submitted to the Executive

Officers for resolution by providing written notice to the other Party formally requesting that the dispute be resolved by the Executive Officers and specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. If a dispute is referred to the Executive Officers, then the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within thirty (30) days after receiving written notification of such dispute or such longer period of time as the Executive Officers may agree in writing. Any final decision mutually agreed to by the Executive Officers with respect to a dispute and set forth in writing shall be conclusive and binding on the Parties. If the Executive Officers cannot resolve such dispute within such thirty (30) days or such other period as agreed by the Executive Officers, such dispute will be resolved as follows:

(a) with respect to any Financial Dispute, such Financial Dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Financial Expert**"). The decision of the Financial Expert shall be final and the costs of the Financial Expert shall be borne by the Parties in accordance with such allocation as the Financial Expert shall determine; and

(b) with respect to any Expedited Matter, such Expedited Matter shall be resolved pursuant to the provisions of **Schedule 1**;

(c) if the dispute is related to (A) whether a given activity is an Alnylam Specific Activity or (B) whether a targeting ligand or other delivery technology proposed under Section 3.6 is a type of Non-Relevant Organ Delivery Technology (each of clauses (A) and (B), an "**Expert Dispute**"), the Parties will mutually agree on an Expert and will submit such matter for resolution by such Expert in accordance with **Schedule 2**, and the determination of the Expert will be binding on the Parties. For avoidance of doubt, the Parties shall be bound by the determination of such Expert; and

(d) with respect to all other disputes, including Legal Disputes, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise subject, however, to Section 13.4.1 and Section 13.9.

13.6 Notices.

13.6.1 Notice Requirements. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth at its address specified in Section 13.6.2 and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand or one (1) Business Day after it is sent via a reputable international overnight

courier service. Either Party may change its address by giving notice to the other Party in the manner provided above. This Section 13.6.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

13.6.2 Address for Notice.

If to Regeneron, to:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel

If to Alnylam, to:

Alnylam Pharmaceuticals, Inc.
300 Third Street
Cambridge, Massachusetts 02142
Attention: Legal Department

13.7 Entire Agreement; Amendments.

13.7.1 This Agreement[, the Supply Agreement (if any) and the Quality Agreement (if any),][101] and the Master Agreement, together with the schedules attached hereto and thereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement[, the Supply Agreement (if any) and the Quality Agreement (if any),][102] or the Master Agreement. In the event of a conflict between the provisions of this Agreement and the Master Agreement with respect to the Target Program (or the Target or Collaboration Products thereunder), the provisions of this Agreement shall control. For the avoidance of doubt, the Parties agree and acknowledge that from and after the Effective Date, there shall be no additional Development, Manufacturing or Commercialization activities with respect to the Target Program or the Exploitation of Collaboration Products pursuant to the Master Agreement.

[101] Note to Draft: Delete this bracketed language if Alnylam is Licensee.
[102] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

13.7.2 No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 LIMITATION OF DAMAGES. IN NO EVENT SHALL LICENSEE OR LICENSOR BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 13.8 IS INTENDED TO LIMIT OR RESTRICT (A) LIABILITY FOR BREACH OF SECTION 6.7.1 OR ARTICLE 9 OR (B) THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER AS SET FORTH IN SECTION 11.1 WITH RESPECT TO CLAIMS.

13.9 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Section 6.7 and ARTICLE 9 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Article may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Each Party hereby waives any requirement that the other Party, as a condition for obtaining any such relief (a) post a bond or other security or (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 13.9 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

13.10 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

13.11 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

13.12 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.13 Relationship of the Parties. It is expressly agreed that Licensor, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture, or agency. Neither Licensor, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

13.14 Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

13.15 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or schedule shall mean references to such Article, Section or schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

13.16 Schedules. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

13.17 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The

captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

REGENERON PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

[SIGNATURE PAGE TO LICENSE AGREEMENT]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

ALNYLAM PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

Schedule 1

Expedited Dispute Resolution

[***]

Schedule 2

Expert Resolution

[***]

Schedule 1.63

Excluded Agreements

Schedule 1.66

Existing Alnylam CMOs

Schedule 1.67

Existing Licensee In-Licenses

1. Existing Licensee In-Licenses:

[2. Additional Alnylam In-Licenses:][103]

[103] Note to Draft: Delete this bracketed language if Alnylam is Licensor.

Schedule 1.68

Existing Licensee Third Party Agreements

Schedule 1.69

Existing Licensor In-Licenses

1. Existing Licensor In-Licenses:

[2. Additional Alnylam In-Licenses:][104]

[104] Note to Draft: Delete this bracketed language if Alnylam is Licensee.

Schedule 1.70

Existing Licensor Third Party Agreements

Schedule 1.115

Licensee Product-Specific Patents

[Schedule 1.128][105]

[Licensor Core Technology Patents]

[105] Note to Draft: Delete this **Schedule 1.128** if Regeneron is Licensor.

Schedule 1.135

Licensor Product-Specific Patents

Schedule 1.140

Manufacturing Cost

[***]

[Schedule 1.163][106]

[***]

[***]

[106] Note to Draft: Include this **Schedule 1.163** only if the Target was a CNS Target or Eye Target under the Master Agreement and there were Competing Products Directed to the Target that were permitted with respect to the Target pursuant to subsection (C) or (D) of Section 5.7.1(a) of the Master Agreement, as applicable. If included, the schedule should include the applicable exceptions.

[Schedule 1.164][107]

[***]

[107] Note to Draft: Include this **Schedule 1.164** only if there was a Permitted Dual Sequence for the Target under the Master Agreement.

Schedule 1.213

Target

[Schedule 3.1.5][108]

Permitted Alnylam Third Party Providers

[108] Note to Draft: Delete this **Schedule 3.1.5** if Alnylam is Licensee.

[Schedule 5.2.1(b)][109]

[Key Terms for Supply of Early Stage Supply Requirements

[***]

[109] Note to Draft: Delete this **Schedule 5.2.1(b)** if Alnylam is Licensee.

Schedule 10.2

Licensor Disclosure Schedule[110]

1. **Introduction**

1.1 All capitalized terms used but not defined in this **Schedule 10.2** shall have the meanings as defined in the Agreement, unless otherwise provided.

1.2 Inclusion of any item in this **Schedule 10.2** (a) does not represent a determination that such item is material or establish a standard of materiality, (b) does not represent a determination that such item did not arise in the ordinary course of business, (c) does not represent a determination that the transactions contemplated by the Agreement require the consent of Third Parties, and (d) shall not constitute, or be deemed to be, an admission to any Third Party concerning such item.

2. **No Warranty or Covenant**

Neither this **Schedule 10.2** nor any disclosure made in or by virtue of this **Schedule 10.2** will constitute or imply any representation, warranty, assurance or undertaking by Licensor not expressly set out in the Agreement.

3. **Disclosures**

The section numbers below correspond to the section numbers of Licensor's representations and warranties in the Agreement.

[110] Note to Draft: Any exceptions to be added shall be limited to the exceptions provided in the Program Data Package delivered by Licensor under the Master Agreement.

[Schedule 10.2.9][111]

[Certain Obligations under Existing Licensor In-Licenses]

[111] Note to Draft: Delete this **Schedule 10.2.9** if Alnylam is Licensor.

[Schedule 10.2.13][112]

[Certain Obligations under Existing Licensor In-Licenses]

[Part 1: Payment Obligations]

[Part 2: Additional Obligations]

[112] Note to Draft: Delete this **Schedule 10.2.13** if Regeneron is Licensor.

Schedule 10.3

Licensee Disclosure Schedule[113]

[***]

[113] Note to Draft: Any exceptions to be added shall be limited to the exceptions provided in the Program Data Package delivered by Licensee under the Master Agreement.

Schedule 12.6.1

Effects of Termination

[***]

Schedule 12.6.2

Effects of Termination

[***]

Exhibit 10.5

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

INVESTOR AGREEMENT

BY AND BETWEEN

REGENERON PHARMACEUTICALS, INC.

AND

ALNYLAM PHARMACEUTICALS, INC.

DATED AS OF APRIL 8, 2019

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(continued)

INVESTOR AGREEMENT

THIS INVESTOR AGREEMENT (this "**Agreement**") is made as of April 8, 2019, by and between Regeneron Pharmaceuticals, Inc. (the "**Investor**"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and Alnylam Pharmaceuticals, Inc. (the "**Company**"), a Delaware corporation with its principal place of business at 300 Third Street, Cambridge, Massachusetts 02142.

WHEREAS, the Stock Purchase Agreement, dated as of April 8, 2019 by and between the Investor and the Company (the "**Purchase Agreement**") provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of shares (the "**Purchased Shares**") of the Company's common stock, par value $0.01 per share (the "**Common Stock**"), or the Company's Series A Redeemable Convertible Preferred Stock, par value $0.01 per share (the "**Preferred Stock**"); and

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Investor and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Investor and its Affiliates, and it is a condition to the execution of the Purchase Agreement that this Agreement be executed and delivered by the Investor and the Company.

NOW, THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. As used in this Agreement, the following terms shall have the following meanings:

(a) "**Acquisition Proposal**" shall have the meaning set forth in Section 3.1(c).

(b) "**Affiliate**" shall mean, with respect to any Person, another Person which Controls, is Controlled by or is under common Control with such Person. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

(c) "**Affiliate Irrevocable Proxy**" shall have the meaning set forth in Section 5.1.

(d) "**Agreement**" shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.

(e) "**beneficial owner**," "**beneficially owns**," "**beneficial ownership**" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.

(f) "**Business Day**" shall mean a day on which commercial banking institutions in New York, New York are open for business.

(g) "**Change of Control**" shall mean, with respect to an entity, any of the following events: (i) any Person is or becomes the beneficial owner (except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by the capital stock of such entity; (ii) such entity consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such entity, other than (A) a merger or consolidation which would result in the voting securities of the entity outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of the entity or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, (B) a merger or consolidation which would result in a majority of the board of directors of the combined entity being comprised of members of the board of directors of the pre-transaction entity immediately following the consummation of such merger or consolidation, or (C) a merger or consolidation effected to implement a recapitalization of such entity (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all shares of capital stock of such entity or (iii) such entity conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly owned Affiliate of such entity.

(h) "**Closing**" shall have the meaning set forth in the Purchase Agreement.

(i) "**Co-Co Collaboration Agreement**" shall have the meaning set forth in the Collaboration Agreement, and as may be amended or modified from time to time pursuant to the terms of the Collaboration Agreement.

(j) "**Collaboration Agreement**" shall mean the Master Agreement by and between the Investor and the Company, dated as of April 8, 2019.

(k) "**Common Stock**" shall have the meaning set forth in the Preamble to this Agreement.

(l) "**Common Stock Equivalents**" shall mean any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock.

(m) "**Company**" shall have the meaning set forth in the Preamble to this Agreement.

(n) "**Control**" (including the terms "Controlled by" or "under common Control with") shall mean the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to Control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

(o) "**Controlled Affiliate**" shall mean, with respect to a Person, an Affiliate of such Person Controlled by such Person.

(p) "**Demand Request**" shall have the meaning set forth in Section 2.1.

(q) "**Disposition**" or "**Dispose of**" shall mean any (i) offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock or Common Stock Equivalents, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

(r) "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder.

(s) "**Extraordinary Matter**" shall have the meaning set forth in Section 5.2.

(t) "**Filing Date**" shall mean (i) with respect to any Registration Statement to be filed on Form S-1 (or any applicable successor form), ninety (90) days after receipt by the Company of a Demand Request for such Registration Statement and (ii) with respect to any Registration Statement to be filed on Form S-3 (or any applicable successor form), thirty (30) days after receipt by the Company of a Demand Request for such Registration Statement.

(u) "**Governmental Authority**" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

(v) "**Holders**" shall mean (but, in each case, only for so long as such Person remains an Affiliate of the Investor) the Investor and any Permitted Transferee thereof, if any, in accordance with Section 2.13.

(w) "**Initiating Holder**" shall have the meaning set forth in Section 2.3.

(x) "**Interference**" shall have the meaning set forth in Section 2.6.

(y) "**Investor**" shall have the meaning set forth in the Preamble to this Agreement.

(z) "**Irrevocable Proxy**" shall have the meaning set forth in Section 5.1.

(aa) "**Law**" or "**Laws**" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

(bb) "**License Agreement**" shall have the meaning set forth in the Collaboration Agreement, and as may be amended or modified from time to time pursuant to the terms of the Collaboration Agreement.

(cc) "**Lock-Up Securities**" shall have the meaning set forth in Section 4.1.

(dd) "**Lock-Up Term**" shall have the meaning set forth in Section 4.1.

(ee) "**Modified Clause**" shall have the meaning set forth in Section 7.7.

(ff) "**Offeror**" shall have the meaning set forth in Section 3.1(c).

(gg) "**Other Holders**" shall mean any Person having rights to participate in a registration of the Company's securities.

(hh) "**Permitted Transferee**" shall mean an Affiliate of the Investor; provided, however, that no such Affiliate shall be deemed a Permitted Transferee for any purpose under this Agreement unless (I) the Permitted Transferee, prior to or simultaneously with such transfer or assignment, shall have agreed in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement, and (II) the Investor shall, within five (5) days prior to such transfer, furnish to the Company written notice of the name and address of such Permitted Transferee, details of its status as a Permitted Transferee and details of the Registrable Securities with respect to which such registration rights are being assigned.

(ii) "**Person**" shall mean any individual, limited liability company, partnership, firm, corporation, association, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

(jj) "**Preferred Stock**" shall have the meaning set forth in the Preamble to this Agreement.

(kk) "**Prospectus**" shall mean the prospectus forming a part of any Registration Statement, as supplemented by any and all prospectus supplements and as amended by any and all amendments (including post-effective amendments) and including all material incorporated by reference or explicitly deemed to be incorporated by reference in such prospectus.

(ll) "**Purchase Agreement**" shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.

(mm) "**Purchased Shares**" shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares.

(nn) "**registers**," "**registered**," and "**registration**" refer to a registration effected by preparing and filing a Registration Statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document by the SEC.

(oo) "**Registrable Securities**" shall mean (i) the Purchased Shares (if the Purchased Shares are Common Stock) or the shares of Common Stock issuable or issued upon conversion of the Purchased Shares (if the Purchased Shares are Preferred Stock), in either case together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (i) of this definition, excluding in all cases, however, (A) any Registrable Securities if and after they have been transferred to a Permitted Transferee in a transaction in connection with which registration rights granted hereunder are not assigned, (B) any Registrable Securities sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction or (C) Registrable Securities eligible for resale pursuant to Rule 144(b)(1)(i) under the Securities Act.

(pp) "**Registration Expenses**" shall mean all expenses incurred by the Company in connection with any Required Registration pursuant to Section 2.1 or the Company's compliance with Section 2.8, including, without limitation, all registration and filing fees, fees and

expenses of compliance with securities or blue sky Laws (including reasonable fees and disbursements of counsel in connection with blue sky qualifications of any Registrable Securities), expenses of printing (i) certificates for any Registrable Securities in a form eligible for deposit with the Depository Trust Company or (ii) Prospectuses if the printing of Prospectuses is requested by Holders, messenger and delivery expenses, fees and disbursements of counsel for the Company and its independent certified public accountants (including the expenses of any management review, cold comfort letters or any special audits required by or incident to such performance and compliance), Securities Act liability insurance (if the Company elects to obtain such insurance), the reasonable fees and expenses of any special experts retained by the Company in connection with such registration, fees and expenses of other Persons retained by the Company and the reasonable fees and expenses (such fees and expenses not to exceed [***]) of one (1) counsel for the Holders of Registrable Securities in each Required Registration, selected by the Holders of a majority of the Registrable Securities to be included in such Required Registration. In addition, the Company will pay its internal expenses (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Registrable Securities to be registered on each securities exchange, if any, on which equity securities issued by the Company are then listed or the quotation of such securities on any national securities exchange on which equity securities issued by the Company are then quoted.

(qq) "**Registration Rights Term**" shall have the meaning set forth in Section 2.1.

(rr) "**Registration Statement**" shall mean any registration statement of the Company under the Securities Act that covers any of the Registrable Securities pursuant to the provisions of this Agreement, including the related Prospectus, all amendments and supplements to such registration statement (including post-effective amendments), and all exhibits and all materials incorporated by reference or explicitly deemed to be incorporated by reference in such Registration Statement.

(ss) "**Required Period**" with respect to a Required Registration shall mean the earlier of (i) the date on which all Registrable Securities covered by such Required Registration are sold pursuant thereto and (ii) one hundred twenty (120) days following the first day of effectiveness of the Registration Statement for such Required Registration, in each case subject to extension as set forth herein; provided, however, that in no event will the Required Period expire prior to the expiration of the applicable period referred to in Section 4(a)(3) of the Securities Act and Rule 174 promulgated thereunder; provided, further, however, that (i) such one-hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended, if necessary, to keep the Registration Statement effective until the earlier of such time as all such Registrable Securities registered on such Registration Statement (A) are sold or (B) may be sold in any three month period pursuant to Rule 144.

(tt) "**Required Registration**" shall have the meaning set forth in Section 2.1.

(uu) "**Research Term**" shall have the meaning set forth in the Collaboration Agreement, and as may be amended or modified from time to time pursuant to the terms of the Collaboration Agreement.

(vv) "**SEC**" shall mean the United States Securities and Exchange Commission.

(ww) "**Securities Act**" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.

(xx) "**Selling Expenses**" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement.

(yy) "**Shares of Then Outstanding Common Stock**" shall mean, at any time, the most recent number of issued and outstanding shares of Common Stock reported by the Company in the Company SEC Documents (as defined in the Purchase Agreement), plus shares of Common Stock issuable upon conversion of issued and outstanding Preferred Stock at such time.

(zz) "**Standstill Limit**" shall mean thirty percent (30%) of the Shares of Then Outstanding Common Stock.

(aaa) "**Standstill Parties**" shall have the meaning set forth in Section 3.1.

(bbb) "**Standstill Term**" shall have the meaning set forth in Section 3.1.

(ccc) "**Third Party**" shall mean any Person other than the Investor, the Company or any of their respective Affiliates.

(ddd) "**Underwritten Registration**" or "**Underwritten Offering**" shall mean a registration in which Registrable Securities are sold to an underwriter for reoffering to the public.

(eee) "**Violation**" shall have the meaning set forth in Section 2.11(a).

2. Registration Rights. Effective as of the Closing:

2.1 Required Registration. If, at any time after the expiration of the Lock-Up Term but no later than the tenth (10^{th}) anniversary of such expiration (the "**Registration Rights Term**"), the Company receives from any Holder or Holders a written request or requests (each, a "**Demand Request**") that the Company file a Registration Statement under the Securities Act to effect the registration (a "**Required Registration**") of Registrable Securities, the Company shall use all reasonable efforts to file a Registration Statement covering such Holders' Registrable

Securities as soon as practicable (and by the applicable Filing Date) and shall use all reasonable efforts to, as soon as practicable thereafter, effect the registration of the Registrable Securities to permit or facilitate the sale and distribution in an Underwritten Offering of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such Demand Request, subject however, to the conditions and limitations set forth herein; provided, however, that the Company shall not be obligated to effect any registration of Registrable Securities upon receipt of a Demand Request pursuant to this Section 2.1 if:

(i) the Company has already completed three (3) Required Registrations;

(ii) (A) in the event that the market value of all Registrable Securities outstanding is equal to or greater than fifty million dollars ($50,000,000), the market value of the Registrable Securities proposed to be included in the registration, based on the average closing price during the ten (10) consecutive trading days period prior to the making of the Demand Request, is less than fifty million dollars ($50,000,000) or (B) in the event that the market value of all Registrable Securities outstanding is less than fifty million dollars ($50,000,000), the market value of the Registrable Securities proposed to be included in the registration, based on the average closing price during the ten (10) consecutive trading days period prior to the making of the Demand Request, is less than the lesser of (x) twenty-five million dollars ($25,000,000) or (y) the total market value of Registrable Securities outstanding.

(iii) the Company furnishes to the Holders a certificate signed by an authorized officer of the Company stating that (A) within sixty (60) days after receipt of the Demand Request under this Section 2.1, the Company will file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (x) issuable pursuant to an employee stock option, stock purchase or similar plan, (y) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act or (z) in which the only securities being registered are securities issuable upon conversion of debt securities which are also being registered), provided, that the Company is actively employing good faith efforts to cause such registration statement to become effective or (B) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the Registration Statement, and in the good faith judgment of the Company's Board of Directors, such disclosure would be detrimental to the Company and its stockholders at such time (in which case, the Company shall disclose the matter as promptly as reasonably practicable and thereafter file the Registration Statement, and each Holder agrees not to disclose any information about such material transaction to Third Parties until such disclosure has occurred or such information has entered the public domain other than through breach of this provision by such Holder), provided, however, that the Company shall have the right to only defer the filing of the Registration Statement pursuant to this subsection once in any twelve (12) month period and, such deferral may not exceed a period of more than ninety (90) days after receipt of a Demand Request;

(iv) the Company has, within the twelve (12) month period preceding the date of the Demand Request, already effected one (1) Required Registration for any Holder pursuant to this Section 2.1; or

(v) at any time during the period between the Company's receipt of the Demand Request and the completion of the Required Registration, any Holder is in breach of or has failed to cause its Controlled Affiliates to comply with the obligations and restrictions of Sections 3, 4 or 5 of this Agreement, and such breach or failure is ongoing and has not been remedied; it being understood that (A) a one-time, inadvertent and de minimis breach of Section 4 shall not be deemed to be a breach of the obligations and restrictions under Section 4 for purposes of this Section 2.1(v) and (B) a de minimis breach of Section 3.1(a) hereof, or an inadvertent breach of Section 3.1(g) hereof arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 3.1, shall not be deemed to be a breach of the obligations and restrictions under Section 3.1 for purposes of this Section 2.1(v).

2.2 Company Registration. Effective from the expiration of the Lock-Up Term until the earlier of (a) the tenth (10^{th}) anniversary of such expiration and (b) the date on which the Holders no longer beneficially own at least one percent (1%) of the Shares of Then Outstanding Common Stock, (provided, however, if the Holders reacquire beneficial ownership representing at least one percent (1%) of the Shares of Then Outstanding Common Stock at any time within ten (10) year period set forth in clause (a) of this Section 2.2, the provisions of this Section 2.2 shall automatically again become applicable to the Holders) the Company shall notify the Holders in writing at least ten (10) days prior to the filing of any Registration Statement including shares of Common Stock by one or more selling stockholders (other than the Holders) ("**Registration Notice**") and will afford each Holder an opportunity, subject to the terms and conditions of this Agreement, to include in such Registration Statement the number of Registrable Securities then held by such Holder that such Holder wishes to include in such Registration Statement. Each Holder desiring to include in any such Registration Statement all or any part of the Registrable Securities held by such Holder shall, within five (5) days after receipt of the Registration Notice, so notify the Company in writing, and in such notification, inform the Company of the number of Registrable Securities such Holder wishes to include in such Registration Statement. If a Holder decides not to include Registrable Securities in any Registration Statement thereafter filed by the Company, such Holder shall nevertheless continue to have the right to include Registrable Securities in any subsequent Registration Statement or Registration Statements as may be filed by the Company with respect to offerings of its securities, all upon the terms and conditions set forth herein. Each Holder shall keep confidential and not disclose to any third party (i) its receipt of any Registration Notice and (ii) any information regarding the proposed offering as to which such notice is delivered, except as required by law, regulation or as compelled by subpoena. If a registration pursuant to this Section 2.2 is an Underwritten Offering, the right of any such Holder to include Registrable

Securities in a registration statement pursuant to this Section 2.2 shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. The Company and all Holders proposing to distribute their Registrable Securities through such underwriting shall enter into an underwriting agreement in customary form with the managing underwriter or underwriters selected for such underwriting. Notwithstanding any other provision of this Section 2, if the managing underwriter for the Underwritten Offering determines in good faith that marketing factors require a limitation of the number of shares of Registrable Securities to be included in such Underwritten Offering and advises the Holders of such determination in writing, then the managing underwriter may exclude shares (including up to 100% of the Registrable Securities) from the registration and the underwriting, with the number of Registrable Securities, if any, included in the registration and the underwriting being allocated to each of the Holders requesting inclusion of their Registrable Securities in such Registration Statement and all other Persons selling shares of Common Stock pursuant to such Registration Statement on a pro rata basis based on the total number of shares of Common Stock then held by each such Holder or other stockholder. Notwithstanding the foregoing, the Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.2 prior to the effectiveness of such registration whether or not any Holder has elected to include securities in such registration.

2.3 Underwritten Registration Required; Priority in Underwritten Offering. The underwriter for any Underwritten Offering requested pursuant to Section 2.1 shall be selected by a majority in interest of the Holders initiating the Required Registration hereunder (such Holder(s) initiating the registration request, the "**Initiating Holders**") and shall be reasonably acceptable to the Company. The right of any Holder to include its Registrable Securities in the Underwritten Offering shall be conditioned upon such Holder's participation in such Underwritten Offering and the inclusion of such Holder's Registrable Securities to the extent provided herein. All Holders requesting the inclusion of their Registrable Securities in such Underwritten Offering shall (together with the Company as provided in Section 2.8(h)) enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such Underwritten Offering. Notwithstanding any other provision of this Section 2, if the managing underwriter for the Underwritten Offering determines in good faith that marketing factors require a limitation of the number of shares of Registrable Securities to be included in such Underwritten Offering, and advises the Holders of such determination in writing, then the Company shall so advise all Holders which requested inclusion of their Registrable Securities in such Underwritten Offering, and the number of shares of Registrable Securities that may be included in such Underwritten Offering shall be allocated among the Holders in proportion (as nearly as practicable) to the amount of Registrable Securities of the Company owned by each Holder; provided, however, that the number of shares of Registrable Securities to be included in such Underwritten Offering shall not be reduced unless all other securities are first entirely

excluded from such Underwritten Offering. In the event the Company advises the Holders of its intent to decrease the total number of Registrable Securities that may be included by the Holders in such Required Registration such that the number of Registrable Securities included in such Required Registration would be less than seventy-five percent (75%) of all Registrable Securities which the Holders requested be included in such Required Registration, then Holders representing a majority of the Registrable Securities requested to be included in such Required Registration will have the right to withdraw, on behalf of all Holders of all Registrable Securities requested to be so included, such Required Registration, in which case, such Required Registration will not count as a Required Registration for the purposes of Section 2.1(i), and the Company shall bear all Registration Expenses in connection therewith; provided, that, the right to withdraw a registration and have it not count as a Required Registration may only be exercised once by the Holders (taken collectively).

2.4 Priority in Required Registration. With respect to any Required Registration of Registrable Securities requested pursuant to Section 2.1, the Company may also (i) propose to sell shares of Common Stock on its own behalf and (ii) provide written notice of such Required Registration to Other Holders and permit all such Other Holders who request to be included in the Required Registration to include any or all Company securities held by such Other Holders in such Required Registration on the same terms and conditions as the Registrable Securities. Notwithstanding the foregoing, if the managing underwriter or underwriters of the Underwritten Offering to which any Required Registration relates advise the Company in writing and advises the Holders of Registrable Securities of such determination in writing, that in its good faith determination, the total amount of securities that such Holders, Other Holders, and the Company intend to include in such Required Registration is in an amount in the aggregate which would adversely affect the success of such Underwritten Offering, then such Required Registration shall include (i) first, all Registrable Securities of the Holders allocated, if the amount is less than all the Registrable Securities requested to be sold, *pro rata* on the basis of the total number of Registrable Securities held by such Holders; and (ii) second, as many other securities proposed to be included in the Required Registration by the Company and any Other Holders, allocated *pro rata* among the Company and such Other Holders, on the basis of the amount of securities requested to be included therein by the Company and each such Other Holder so that the total amount of securities to be included in such Underwritten Offering is the full amount that, in the written opinion of such managing underwriter, can be sold without materially and adversely affecting the success of such Underwritten Offering.

2.5 Revocation of Required Registration. With respect to one (1) Required Registration only, the Holders of at least a majority of the Registrable Securities to be included in a Registration Statement with respect to such Required Registration may, at any time prior to the effective date of such Registration Statement, on behalf of all Holders of all Registrable Securities requested to be included therein, revoke the request to have Registrable Securities

included therein and revoke the request for such Required Registration by providing a written notice to the Company, in which case such Required Registration that has been revoked will be deemed not to have been effected and will not count as a Required Registration for purposes of Section 2.1(i) if, and only if, the Holders of Registrable Securities which had requested inclusion of Registrable Securities in such Required Registration promptly reimburse the Company for all Registration Expenses incurred by the Company in connection with such Required Registration. Notwithstanding the foregoing sentence, the parties agree and acknowledge that the Holders may revoke any Required Registration (without any obligation to reimburse the Company for Registration Expenses incurred in connection therewith) if such revocation is based on (i) a material adverse change in circumstances with respect to the Company and its subsidiaries, taken as a whole, caused by an act or failure to act by the Company or any of its subsidiaries and not known to any Holder at the time the Required Registration was first made or (ii) the Company's failure to comply in any material respect with its obligations hereunder, and any such revocation based on an event described in (i) or (ii) above shall be exercisable at any time and shall not be counted as the one (1) revocation of a Required Registration permitted by the first sentence of this Section 2.5.

2.6 Effective Required Registrations. A Required Registration will not be deemed to be effected for purposes of Section 2.1(i) if the Registration Statement for such Required Registration has (a) not been declared effective by the SEC or (b) become effective in accordance with the Securities Act and the rules and regulations thereunder and not been kept effective for the Required Period. In addition, if after such Registration Statement has been declared or becomes effective, (i) the offering of Registrable Securities pursuant to such Registration Statement is interfered with by any stop order, injunction, or other order or requirement of the SEC or other governmental agency or court such that the continued offer and sale of Registrable Securities being offered pursuant to such Registration Statement would violate applicable Law and such stop order, injunction or other order or requirement of the SEC or other governmental agency or court does not result from any act or omission of any Holder whose Registrable Securities are registered pursuant to such Registration Statement (an "**Interference**") and (ii) any such Interference is not cured within sixty (60) days thereof, such Required Registration will be deemed not to have been effected and will not count as a Required Registration. In the event such Interference occurs and is cured, the Required Period relating to such Registration Statement will be extended by the number of days of such Interference, including the date such Interference is cured.

2.7 Continuous Effectiveness of Registration Statement. The Company will use all reasonable efforts to cause each Registration Statement filed pursuant to this Section 2 to be declared effective by the SEC or to become effective under the Securities Act as promptly as practicable and to keep each such Registration Statement that has been declared or becomes effective continuously effective for the Required Period.

2.8 Obligations of the Company. Whenever required under Section 2.1 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a Registration Statement with respect to such Registrable Securities sought to be included therein; provided that at least five (5) Business Days prior to filing any Registration Statement or Prospectus or any amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder or the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(b) prepare and file with the SEC such amendments and post-effective amendments to any Registration Statement and any Prospectus used in connection therewith as may be necessary to keep such Registration Statement effective for the Required Period, and cause the Prospectus to be supplemented by any required prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act, to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement for the Required Period; provided that at least five (5) Business Days prior to filing any such amendments and post effective amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder or managing underwriter shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder and the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(c) furnish to the Holders of Registrable Securities covered by such Registration Statement and the managing underwriter such numbers of copies of such Registration Statement, each amendment and supplement thereto, the Prospectus included in such Registration Statement (including each preliminary prospectus or free writing prospectus) in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

(d) notify the Holders of Registrable Securities covered by such Registration Statement, promptly after the Company shall receive notice thereof, of the time when such Registration Statement becomes or is declared effective or when any amendment or supplement or any Prospectus forming a part of such Registration Statement has been filed;

(e) notify the Holders of Registrable Securities covered by such Registration Statement promptly of any request by the SEC for the amending or supplementing of such Registration

Statement or Prospectus or for additional information and promptly deliver to such Holders copies of any comments received from the SEC;

(f) notify the Holders promptly of any stop order suspending the effectiveness of such Registration Statement or Prospectus or the initiation of any proceedings for that purpose, and use all reasonable efforts to obtain the withdrawal of any such order or the termination of such proceedings;

(g) use all reasonable efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky Laws of such jurisdictions as shall be reasonably requested by the Holders, use all reasonable efforts to keep each such registration or qualification effective, including through new filings, or amendments or renewals, during the Required Period, and notify the Holders of Registrable Securities covered by such Registration Statement of the receipt of any written notification with respect to any suspension of any such qualification; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, except as may be required by the Securities Act;

(h) enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of the Underwritten Offering pursuant to which such Registrable Securities are being offered;

(i) use all reasonable efforts to obtain: (A) at the time of effectiveness of the Registration Statement covering such Registrable Securities, a "cold comfort letter" from the Company's independent certified public accountants covering such matters of the type customarily covered by "cold comfort letters" as the underwriters may reasonably request; and (B) at the time of any underwritten sale pursuant to such Registration Statement, a "bring-down comfort letter," dated as of the date of such sale, from the Company's independent certified public accountants covering such matters of the type customarily covered by "bring-down comfort letters" as the underwriters may reasonably request.

(j) promptly notify each Holder of Registrable Securities covered by such Registration Statement at any time when a Prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the Prospectus included in such Registration Statement or any offering memorandum or other offering document includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing, and promptly prepare a supplement or amendment to such Prospectus or file any other required document so that, as thereafter delivered to the purchasers of such Registrable Securities, such Prospectus will not contain an untrue statement of material fact or omit to state any fact necessary to make the statements therein not misleading;

(k) permit any Holder of Registrable Securities covered by such Registration Statement, which Holder in its reasonable judgment could reasonably be deemed to be an underwriter with respect to the Underwritten Offering pursuant to which such Registrable Securities are being offered,

or to be a controlling Person of the Company, to reasonably participate in the preparation of such Registration Statement and to require the insertion therein of information to the extent concerning such Holder, furnished to the Company in writing, which in the reasonable judgment of such Holder and its counsel should be included;

(l) in connection with any Underwritten Offering, use all reasonable efforts to obtain an opinion or opinions addressed to the underwriter or underwriters in customary form and scope from counsel for the Company;

(m) upon reasonable notice and during normal business hours, subject to the Company receiving customary confidentiality undertakings or agreements from any Holder of Registrable Securities covered by such Registration Statement or other person obtaining access to Company records, documents, properties or other information pursuant to this subsection (m), make available for inspection by a representative of such Holder and any underwriter participating in any disposition of such Registrable Securities and any attorneys or accountants retained by any such Holder or underwriter, relevant financial and other records, pertinent corporate documents and properties of the Company, and use all reasonable efforts to cause the officers, directors and employees of the Company to supply all information reasonably requested by any such representative, underwriter, attorneys or accountants in connection with the Registration Statement;

(n) with respect to one (1) Required Registration which includes Registrable Securities the market value of which is at least one hundred million dollars ($100,000,000), participate, to the extent requested by the managing underwriter, in efforts extending for no more than three (3) days scheduled by such managing underwriter and reasonably acceptable to the Company's senior management, to sell the Registrable Securities being offered pursuant to such Required Registration (including participating during such period in customary "roadshow" meetings with prospective investors);

(o) use all reasonable efforts to comply with all applicable rules and regulations of the SEC relating to such registration and make generally available to its security holders earning statements satisfying the provisions of Section 11(a) of the Securities Act, provided that the Company will be deemed to have complied with this Section 2.8(o) with respect to such earning statements if it has satisfied the provisions of Rule 158;

(p) if requested by the managing underwriter or any selling Holder, promptly incorporate in a prospectus supplement or post-effective amendment such information as the managing underwriter or any selling Holder reasonably requests to be included therein, with respect to the Registrable Securities being sold by such selling Holder, including, without limitation, the purchase price being paid therefor by the underwriters and with respect to any other terms of the Underwritten Offering of Registrable Securities to be sold in such offering, and promptly make all required filings of such prospectus supplement or post-effective amendment;

(q) cause the Registrable Securities covered by such Registration Statement to be listed on each securities exchange, if any, on which equity securities issued by the Company are then listed; and

(r) reasonably cooperate with each selling Holder and each underwriter participating in the disposition of such Registrable Securities and their respective counsel in connection with filings required to be made with the Financial Industry Regulatory Authority, Inc., if any.

2.9 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself and the Registrable Securities held by it as shall be reasonably necessary to effect the registration of such Holder's Registrable Securities.

2.10 Expenses. Except as specifically provided herein, all Registration Expenses shall be borne by the Company. All Selling Expenses incurred in connection with any registration hereunder shall be borne by the Holders of Registrable Securities covered by a Registration Statement, pro rata on the basis of the number of Registrable Securities registered on their behalf in such Registration Statement.

2.11 Indemnification. In the event any Registrable Securities are included in a Registration Statement under this Agreement:

(a) The Company shall indemnify and hold harmless each Holder including Registrable Securities in any such Registration Statement, any underwriter (as defined in the Securities Act) for such Holder and each Person, if any, who controls such Holder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, against any and all losses, claims, damages or liabilities (joint or several) to which they may become subject under any securities Laws including, without limitation, the Securities Act, the Exchange Act, or any other statute or common law of the United States or any other country or political subdivision thereof, or otherwise, including the amount paid in settlement of any litigation commenced or threatened (including any amounts paid pursuant to or in settlement of claims made under the indemnification or contribution provisions of any underwriting or similar agreement entered into by such Holder in connection with any offering or sale of securities covered by this Agreement), and shall promptly reimburse them, as and when incurred, for any legal or other expenses incurred by them in connection with investigating any claims and defending any actions, insofar as any such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each, a "**Violation**"): (i) any untrue statement or alleged untrue statement of a material fact contained in or incorporated by reference into such Registration Statement, including any preliminary prospectus or final prospectus contained therein or any free writing prospectus or any amendments or supplements thereto, or in any offering memorandum or other offering document relating to the offering and sale of such securities, (ii) the

omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading or (iii) any violation or alleged violation by the Company (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities Law, or any rule or regulation promulgated under any state securities Law, in each case arising from such Registration Statement; provided, however, the Company shall not be liable in any such case for any such loss, claim, damage, liability or action to the extent that it (A) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (B) is caused by such Holder's disposition of Registrable Securities during any period during which such Holder is obligated to discontinue any disposition of Registrable Securities as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities. The Company shall pay, as incurred, any legal or other expenses reasonably incurred by any Person intended to be indemnified pursuant to this Section 2.11(a), in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 2.11(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Company, which consent shall not be unreasonably withheld, conditioned or delayed.

(b) Each Holder including Registrable Securities in a registration statement shall indemnify and hold harmless the Company, each of its directors, each of its officers who has signed the registration statement, each Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, any underwriter, any other Holder selling securities in such registration statement and any controlling Person of any such underwriter or other Holder, against any losses, claims, damages or liabilities (joint or several) to which any of the foregoing Persons may become subject, under liabilities (or actions in respect thereto) which arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation: (i) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (ii) is caused by such Holder's disposition of Registrable Securities during any period during which such Holder is obligated to discontinue any disposition of Registrable Securities as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities. Each such Holder shall pay, as incurred, any legal or other expenses reasonably incurred by any Person intended to be indemnified pursuant to this Section 2.11(b), in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 2.11(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Holder, which consent shall not be unreasonably withheld.

(c) Promptly after receipt by an indemnified party under this Section 2.11 of notice of the commencement of any action (including any action by a Governmental Authority), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.11, deliver to the indemnifying party a written notice of the commencement thereof and the

indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party shall have the right to retain its own counsel, with the reasonable fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.11, but the omission so to deliver written notice to the indemnifying party shall not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.11.

(d) In order to provide for just and equitable contribution to joint liability in any case in which a claim for indemnification is made pursuant to this Section 2.11 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.11 provided for indemnification in such case, the Company and each Holder of Registrable Securities shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in proportion to the relative fault of the Company, on the one hand, and such Holder, severally, on the other hand; provided, however, that in any such case, no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; provided further, however, that in no event shall any contribution under this Section 2.11(d) on the part of any Holder exceed the net proceeds received by such Holder from the sale of Registrable Securities giving rise to such contribution obligation, except in the case of willful misconduct or fraud by such Holder.

(e) The obligations of the Company and the Holders under this Section 2.11 shall survive the completion of any offering of Registrable Securities in a registration statement under this Agreement and otherwise.

2.12 SEC Reports. With a view to making available to the Holders the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell Registrable Securities of the Company to the public without registration, the Company agrees to at any time that it is a reporting company under Section 13 or 15(d) of the Exchange Act:

(a) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and

(b) furnish to any Holder, so long as such Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the

reporting requirements of the Exchange Act, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC (exclusive of Rule 144A) which permits the selling of any Registrable Securities without registration.

2.13 Assignment of Registration Rights. The rights to cause the Company to register any Registrable Securities pursuant to this Agreement shall automatically be assigned in whole or in part (but only with all restrictions and obligations set forth in this Agreement) by a Holder to a Permitted Transferee which acquires Registrable Securities from such Holder.

3. Restrictions on Beneficial Ownership.

3.1 Standstill. During the period from and after the effectiveness of the Collaboration Agreement and expiring upon the expiration or termination of the Research Term, provided that (i) if the Research Term or the Collaboration Agreement is terminated by the Investor pursuant to Section 11.2 or Section 11.3 of the Collaboration Agreement, the expiration date shall be one (1) year after such termination and (ii) if as of the expiration or termination of the Research Term or the Collaboration Agreement the Standstill Parties (as defined below) beneficially own greater than nineteen and ninety-nine one hundredths percent (19.99%) of the Shares of Then Outstanding Common Stock, the expiration date shall be the earlier of (A) two (2) years following the date of such expiration or termination and (B) the date on which the Standstill Parties beneficially own less than fifteen percent (15%) of the Shares of Then Outstanding Common Stock (such period, the "**Standstill Term**"), neither the Investor nor any of its Controlled Affiliates (collectively, the "**Standstill Parties**") shall (and the Investor shall cause its Controlled Affiliates not to), except as expressly approved or invited in writing by the Company:

(a) directly or indirectly, acquire beneficial ownership of shares of Common Stock and/or Common Stock Equivalents, except pursuant to (i) a stock split, stock dividend, recapitalization, reclassification or similar transaction of the Company or (ii) a direct purchase from the Company, or make a tender, exchange or other offer to acquire shares of Common Stock and/or Common Stock Equivalents, if after giving effect to such acquisition, the Standstill Parties would beneficially own more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 3.1(a), if the number of shares constituting Shares of Then Outstanding Common Stock is reduced or if the aggregate ownership of the Standstill Parties is increased as a result of a repurchase by the Company of shares of Common Stock, stock split, stock dividend or a recapitalization of the Company, the Standstill Parties shall not be required to dispose of any of their holdings of shares of Common Stock and/or Common Stock Equivalents even though such action resulted in the Standstill Parties' beneficial ownership totaling more than the Standstill Limit;

(b) directly or indirectly, seek to have called any meeting of the stockholders of the Company, propose or nominate for election to the Company's Board of Directors any person whose

nomination has not been approved by a majority of the Company's Board of Directors or cause to be voted in favor of such person for election to the Company's Board of Directors any shares of Common Stock and/or Common Stock Equivalents;

(c) directly or indirectly, encourage or support a tender, exchange or other offer or proposal by any other Person or group (an "**Offeror**" (which, for the avoidance of doubt, shall not include the Investor or its Affiliates)) the consummation of which would result in a Change of Control of the Company (an "**Acquisition Proposal**"); provided, however, that from and after the filing of a Schedule 14D-9 (or successor form of Tender Offer Solicitation/Recommendation Statement under Rule 14D-9 of the Exchange Act) by the Company recommending that stockholders accept any such offer, the Investor shall not be prohibited from taking any of the actions otherwise prohibited by this Section 3.1(c) for so long as the Company maintains and does not withdraw such recommendation;

(d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Exchange Act) in opposition to the recommendation of a majority of the Company's Board of Directors with respect to any matter, or seek to influence any Person, with respect to voting of any shares of Common Stock and/or Common Stock Equivalents;

(e) deposit any shares of Common Stock and/or Common Stock Equivalents in a voting trust or subject any shares of Common Stock and/or Common Stock Equivalents to any arrangement or agreement with respect to the voting of such shares of Common Stock and/or Common Stock Equivalents;

(f) propose (i) any merger, consolidation, business combination, tender or exchange offer, purchase of the Company's assets or businesses, or similar transaction involving the Company or (ii) any recapitalization, restructuring, liquidation or other extraordinary transaction with respect to the Company;

(g) act in concert with any Third Party to take any action in clauses (a) through (f) above, or form, join or participate in a "partnership, limited partnership, syndicate, or other group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any voting securities of the Company;

(h) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in (a) through (g) above; or

(i) request or propose to the Company's Board of Directors, any member(s) thereof or any officer of the Company that the Company amend, waive, or consider the amendment or waiver of, any provisions set forth in this Section 3.1 (including this clause (i));

provided, however, that (A) nothing contained in this Section 3.1 shall prohibit the Investor from making confidential, unsolicited, non-public proposals to the Company for a transaction of the type described in the foregoing clause (f) that would result in a Change of Control of the Company, (B) the mere voting in

accordance with Section 5 hereof of any voting securities of the Company held by the Investor or its Controlled Affiliates shall not constitute a violation of any of clauses (a) through (h) above, and (C) nothing contained in this Section 3.1 shall prohibit the Investor from proposing to the applicable committee of the Company's Board of Directors (and not pursuant to the advance notice provisions set forth in the Company's bylaws), in a confidential, non-public manner, potential director candidates for consideration by such committee, which candidates the Investor believes would be in the best interest of the Company and its stockholders.

4. Restrictions on Dispositions.

4.1 Lock-Up. From and after the Closing and until the earlier of (i) the four-year anniversary of the date of the Closing and (ii) the termination of the Collaboration Agreement (the "**Lock-Up Term**"), without the prior approval of the Company, the Investor shall not, and shall cause its Controlled Affiliates not to, Dispose of (x) any of the Purchased Shares or any shares of Common Stock beneficially owned by any Standstill Party as of the closing of the Collaboration Agreement, together with any shares of capital stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares or shares of capital stock described in clause (x) of this sentence (collectively, the "**Lock-Up Securities**"); provided, however, that the foregoing shall not prohibit the Investor from transferring any of the Lock-Up Securities to a Permitted Transferee in accordance with and subject to the terms of Section 2.13.

4.2 Sale Limitations. Subject to the restrictions set forth in Section 4.1 and except for any transfer of Registrable Securities by the Investor to a Permitted Transferee in accordance with and subject to the terms of Sections 2.12 and 4.1, if at any time the Investor and its Controlled Affiliates beneficially own at least nine and nine-tenths percent (9.9%) of the Shares of Then Outstanding Common Stock, then until such time as the Investor and its Controlled Affiliates beneficially own less than five percent (5%) of the Shares of Then Outstanding Common Stock, the Investor shall not, and shall cause its Controlled Affiliates not to, Dispose of any shares of Common Stock and/or Common Stock Equivalents except (i) pursuant to a registered underwritten public offering in accordance with Section 2, (ii) in a manner consistent with the volume limitations set forth in Rule 144 under the Securities Act (whether or not such limitations would by their terms apply to such sales) or (iii) in any transaction approved by the Company; provided, however, that in any Underwritten Offering in accordance with Section 2.1, the Holders whose Registrable Securities are included in such Underwritten Offering shall request that the underwriter for such Underwritten Offering, and shall require that the underwriter for such Underwritten Offering shall agree in writing to, use all reasonable efforts to make as broad a distribution as reasonably practical and to prevent any Person, or Affiliates of

such Person from purchasing in such offering Registrable Securities which would constitute, or result in such Person, together with such Person's Affiliates, having beneficial ownership of, five percent (5%) or more of the total Shares of Then Outstanding Common Stock.

4.3 Certain Tender Offers. Notwithstanding any other provision of this Section 4, this Section 4 shall not prohibit or restrict any Disposition of shares of Common Stock and/or Common Stock Equivalents by the Standstill Parties into (a) a tender offer by a Third Party which is not opposed by the Company's Board of Directors (but only after the Company's filing of a Schedule 14D-9, or any amendment thereto, with the SEC disclosing the recommendation of the Company's Board of Directors with respect to such tender offer), unless Investor is then in breach of its obligations pursuant to Section 3.1 with respect to the tender offer or (b) an issuer tender offer by the Company.

4.4 Offering Lock-Up. The Holders shall, if requested by the Company and an underwriter of Common Stock of the Company, agree not to Dispose of any shares of Common Stock and/or Common Stock Equivalents for a specified period of time, such period of time not to exceed ninety (90) days. Such agreement shall be in writing in a form satisfactory to the Company, the underwriter(s) in such offering and shall contain customary exceptions to the restrictions set forth therein. The Company may impose stop transfer instructions with respect to the shares of Common Stock and/or Common Stock Equivalents to the extent consistent with any such agreement until the end of the specified period of time. The foregoing provisions of this Section 4.4 shall apply to the Holders only if the Company's directors, officers and any beneficial owners of an equal or greater number of shares of Common Stock that are party to a collaboration, license or similar agreement with the Company are subject to similar lock-up restrictions. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

5. Voting Agreement.

5.1 Voting of Securities.

(a) From and after the effectiveness of the Collaboration Agreement, other than as permitted by Section 5.2 with respect to Extraordinary Matters, in any vote or action by written consent of the stockholders of the Company (including, without limitation, with respect to the election of directors), the Investor shall, and shall cause its Controlled Affiliates to, vote or execute a written consent with respect to all voting securities of the Company as to which they are entitled to vote or execute a written consent in accordance with the recommendation of the Company's Board of Directors.

(b) In furtherance of this Section 5.1, the Investor hereby irrevocably appoints the Company and any individuals designated by the Company, and each of them individually, as

the attorneys, agents and proxies, with full power of substitution and re-substitution in each of them, for the Investor, and in the name, place and stead of the Investor, to vote (or cause to be voted) or, if applicable, to give consent, in such manner as each such attorney, agent and proxy or his substitute shall in its, his or her sole discretion deem appropriate or desirable with respect to such matters as set forth in Section 5.1(a) with respect to all voting securities (whether taking the form of Common Stock or other voting securities of the Company) with respect to which the Investor is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting or, if applicable, to give written consent with respect thereto (the "**Irrevocable Proxy**"). This Irrevocable Proxy is coupled with an interest, shall be irrevocable and binding on any successor in interest of the Investor and shall not be terminated by operation of law upon the occurrence of any event. This Irrevocable Proxy shall operate to revoke and render void any prior proxy as to voting securities of the Company heretofore granted by the Investor which is inconsistent herewith. Notwithstanding the foregoing, the Irrevocable Proxy shall be effective if, at any annual or special meeting of the stockholders of the Company (or any consent in lieu thereof) and at any adjournments or postponements of any such meetings, the Investor (A) fails to appear or otherwise fails to cause its voting securities of the Company to be counted as present for purposes of calculating a quorum, or (B) fails to vote such voting securities in accordance with Section 5.1(a), in each case at least five (5) Business Days prior to the date of such shareholders' meeting (or within five (5) Business Days prior to the effective time of an action to be taken by written consent in lieu of such shareholders' meeting). The Irrevocable Proxy shall terminate upon the earlier of the expiration or termination of the voting agreement set forth in this Section 5.1.

(c) The Investor shall cause any Controlled Affiliate of the Investor that may from time to time own of record (or the record holder holding on behalf of such Controlled Affiliate if owned beneficially) voting securities of the Company (whether taking the form of Common Stock or other voting securities of the Company), if and when requested by the Company from time to time, to promptly execute and deliver to the Company an irrevocable proxy, substantially in the form of Exhibit A attached hereto, and irrevocably appoint the Company and any individuals designated by the Company, and each of them individually, with full power of substitution and resubstitution, as its attorney, agent and proxy to vote (or cause to be voted) or to give consent with respect to, all of the voting securities of the Company as to which such Controlled Affiliate is entitled to vote, in such manner as each such attorney, agent and proxy or his substitute shall in its, his or her sole discretion deem appropriate or desirable with respect to the matters set forth in this Section 5.1 (the "**Affiliate Irrevocable Proxy**"). The Investor acknowledges, and shall cause its Controlled Affiliates to acknowledge, that any such proxy executed and delivered shall be coupled with an interest, shall constitute, among other things, an inducement for the Company to enter into this Agreement, shall be irrevocable and binding on any successor in interest of such Controlled Affiliate and shall not be terminated by operation of Law upon the occurrence of any event. Such proxy shall operate to revoke and render void any prior proxy as to any voting securities of the Company heretofore granted by such Controlled Affiliate, to the extent it is inconsistent herewith. The Investor acknowledges and agrees that it shall be a condition to any proposed transfer of voting securities of the Company by the Investor to such Controlled Affiliate that such Controlled Affiliate execute and deliver to the Company an Affiliate Irrevocable Proxy, and that any purported transfer shall be void and of no force or effect if such Affiliate Irrevocable Proxy is not so executed and delivered at the closing of

such transfer. Such proxy shall terminate upon the earlier of the expiration or termination of this Section 5.1.

5.2 Certain Extraordinary Matters. The Investor and its Controlled Affiliates may vote, or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as they may determine in their sole discretion, with respect to the following matters (each such matter being an "**Extraordinary Matter**"):

(a) any transaction which would result in a Change of Control of the Company;

(b) any liquidation or dissolution of the Company; and

(c) from and after expiration or termination of the Standstill Term, any contested election of directors to the Company's Board of Directors.

5.3 Quorum. From and after the effectiveness of the Collaboration Agreement, in furtherance of Section 5.1, the Investor shall be, and shall cause each of its Controlled Affiliates to be, present in person or represented by proxy at all meetings of stockholders to the extent necessary so that all voting securities of the Company as to which they are entitled to vote shall be counted as present for the purpose of determining the presence of a quorum at such meeting.

6. Termination of Certain Rights and Obligations.

6.1 Termination of Registration Rights. Except for Section 2.11, which shall survive until the expiration of any applicable statutes of limitation, Section 2 shall terminate automatically and have no further force or effect upon the earliest to occur of:

(a) the expiration of the Registration Rights Term;

(b) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

(c) a liquidation or dissolution of the Company.

6.2 Termination of Standstill Agreement. Section 3 shall terminate and have no further force or effect, upon the earliest to occur of:

(a) provided that none of the Standstill Parties has violated Section 3.1(c), (d) or (f) with respect to the Offeror referred to in this clause (a), if at any time an Offeror:

(i) enters into a definitive agreement providing for the merger, consolidation or other business combination involving the Company, in each case, the consummation of which would result in a Change of Control of the Company;

(ii) enters into a definitive agreement providing for the purchase or other acquisition of, or purchases or otherwise acquires, all or substantially all of the consolidated assets of the Company;

(iii) enters into a definitive agreement providing for the purchase or other acquisition of, or purchases or otherwise acquires, in each case from the Company, shares of Common Stock or Common Stock Equivalents, such that, following such purchase or acquisition, such Offeror becomes the beneficial owner of securities representing more than thirty percent (30%) of the voting power of the Company; provided, however, that if such Offeror enters into a standstill with the Company on substantially similar terms to those set forth in Section 3 hereof, the foregoing threshold of beneficial ownership of securities shall instead be fifty percent (50%); or

(iv) commences a tender offer or exchange offer with respect to securities representing 50% or more of the voting power of the Company, unless the Company files a recommendation with the SEC within ten (10) Business Days following the commencement of such tender offer or exchange offer pursuant to which the Company's Board of Directors advises the Company's stockholders to reject such tender offer or exchange offer;

(b) the expiration of the Standstill Term;

(c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

(d) a liquidation or dissolution of the Company;

provided, however, that if Section 3 terminates due to clause (a) above and such agreement is abandoned and no other similar transaction has been announced and not abandoned or terminated within ninety (90) days thereafter, the restrictions contained in Section 3 shall again be applicable until otherwise terminated pursuant to this Section 6.2.

6.3 Termination of Restrictions on Dispositions. Section 4 (other than Section 4.4) shall terminate and have no further force or effect upon the earliest to occur of:

(a) the consummation by an Offeror of a Change of Control of the Company;

(b) a liquidation or dissolution of the Company;

(c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

(d) on or following the [***] anniversary of the Closing [***]; provided, that a termination pursuant to this Section 6.3(d) shall become effective on the [***] day following the delivery of written notice to the Company by the Investor of [***]; provided, however, that this Section 6.3(d) shall terminate automatically and be of no further force and effect upon a Change of Control of the Investor.

6.4 Termination of Voting Agreement . Section 5 shall terminate and have no further force or effect upon the earliest to occur of:

(a) the consummation by an Offeror of a Change of Control of the Company;

(b) a liquidation or dissolution of the Company;

(c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act;

(d) the last to occur of (i) the termination of the research collaboration pursuant to Section 11.2 of the Collaboration Agreement, (ii) the termination of the Collaboration Agreement pursuant to Section 11.3 of the Collaboration Agreement and (iii) the expiration of the last-to-expire Royalty Term under (and as defined in) all Co-Co Collaboration Agreements and License Agreements; and

(e) the date on which the Holders together no longer beneficially own at least one percent (1%) of the Shares of Then Outstanding Common Stock; provided, however, that if Section 5 terminates pursuant to this clause (e) and the Holders together thereafter reacquire beneficial ownership of more than one percent (1%) of the Shares of Then Outstanding Common Stock, then the provisions of Section 5 shall thereafter be effective until otherwise terminated pursuant to this Section 6.4.

6.5 Termination of the Offering Lock-Up. Section 4.4 shall terminate and have no further force or effect upon the earliest to occur of:

(a) the consummation by an Offeror of a Change of Control of the Company;

(b) a liquidation or dissolution of the Company;

(c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act;

(d) the expiration of the Standstill Term; and

(e) the date on which the Holders together no longer beneficially own at least one percent (1%) of the Shares of Then Outstanding Common Stock; provided, however, that if Section 4.4 terminates pursuant to this clause (e) and the Holders together thereafter reacquire beneficial ownership of more than one percent (1%) of the Shares of Then Outstanding Common Stock, then the provisions of Section 4.4 shall thereafter be effective until otherwise terminated pursuant to this Section 6.5.

6.6 Effect of Termination. No termination pursuant to any of Sections 6.1, 6.2, 6.3, 6.4 or 6.5 shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

7. Miscellaneous.

7.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 7.3 or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

7.2 Waiver. Waiver by a party of a breach hereunder by another party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

7.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Any party may change its address by giving notice to the other parties in the manner provided above.

7.4 Entire Agreement. This Agreement and the Purchase Agreement contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

7.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the parties hereto.

7.6 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

7.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to

avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

7.8 Assignment. Neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (a) the prior written consent of the Company in the case of any assignment by the Investor, except as provided by Section 2.13 with respect to the Investor's assignment to a Permitted Transferee; or (b) the prior written consent of the Investor in the case of an assignment by the Company.

7.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

7.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

7.11 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, except with respect to a Permitted Transferee. No Third Party (other than a Permitted Transferee) shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

7.12 No Strict Construction. This Agreement has been prepared jointly and will not be construed against any party.

7.13 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

7.14 Specific Performance. The Company and the Investor hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Controlled Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Controlled Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific

performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

7.15 No Conflicting Agreements. The Investor hereby represents and warrants to the Company that neither it nor any of its Controlled Affiliates is, as of the date of this Agreement, a party to, and agrees that neither it nor any of its Controlled Affiliates shall, on or after the date of this Agreement, enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to each Holder that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into, any agreement or approve any amendment to its Organizational Documents (as defined in the Purchase Agreement) with respect to its securities that conflicts with the rights granted to the Holders in this Agreement. The Company further represents and warrants that the rights granted to the Holders hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.

(*Signature Page Follows*)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Nouhad Husseini
Name: Nouhad Husseini
Title: Vice President

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ John M. Maraganore, Ph.D.

Name: John M. Maraganore, Ph.D.

Title: Chief Executive Officer

EXHIBIT A

FORM OF IRREVOCABLE PROXY

In order to secure the performance of the duties of the undersigned pursuant to Section 5.1 of the Investor Agreement, dated as of April 8, 2019 (the "Agreement"), by and between Regeneron Pharmaceuticals, Inc. and Alnylam Pharmaceuticals, Inc. (the "**Company**"), the undersigned hereby irrevocably appoints the Company and any individual designated by the Company, and each of them individually, as the attorneys, agents and proxies, with full power of substitution and resubstitution in each of them, for the undersigned, and in the name, place and stead of the undersigned, to vote (or cause to be voted) or, if applicable, to give consent, in such manner as each such attorney, agent and proxy or his substitute shall in its, his or her sole discretion deem proper to record such vote (or consent) with respect to such matters as set forth in Section 5.1(a) of the Agreement with respect to all voting securities (whether taking the form of Common Stock or other voting securities of the Company), which the undersigned is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting or, if applicable, to give written consent with respect thereto. This proxy is coupled with an interest, shall be irrevocable and binding on any successor in interest of the undersigned and shall not be terminated by operation of law upon the occurrence of any event. This proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the undersigned which is inconsistent herewith. Notwithstanding the foregoing, this irrevocable proxy shall be effective if, at any annual or special meeting of the stockholders of the Company (or any consent in lieu thereof) and at any adjournments or postponements of any such meetings, the undersigned (A) fails to appear or otherwise fails to cause its voting securities of the Company to be counted as present for purposes of calculating a quorum, or (B) fails to vote such voting securities in accordance with Section 5.1(a) of the Agreement, in each case at least five (5) business days prior to the date of such stockholders' meeting (or within five (5) business days prior to the effective time of an action to be taken by written consent in lieu of such stockholders' meeting). This proxy shall terminate upon the earlier of the expiration or termination of the voting agreement set forth in Section 5.1 of the Agreement.

[_____]

By: __
Name:
Title:

EXHIBIT B

NOTICES

(a) If to the Investor:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel

with a copy to:

Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02110
Attention: Alan Leeds, Esq.
Email: alan.leeds@morganlewis.com
Bryan Keighery, Esq.
Email: bryan.keighery@morganlewis.com

(b) If to the Company:

Alnylam Pharmaceuticals, Inc.
300 Third Street
Cambridge, Massachusetts 02142
Attention: Legal Department

with a copy to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Mitchell S. Bloom, Esq.
Email: mbloom@goodwinlaw.com
Gregg L. Katz, Esq.
Email: gkatz@goodwinlaw.com

Exhibit 10.6

STOCK PURCHASE AGREEMENT

BY AND BETWEEN

REGENERON PHARMACEUTICALS, INC.

AND

ALNYLAM PHARMACEUTICALS, INC.

DATED AS OF APRIL 8, 2019

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STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of April 8, 2019, by and between Regeneron Pharmaceuticals, Inc. (the "**Investor**"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and Alnylam Pharmaceuticals, Inc. (the "**Company**"), a Delaware corporation with its principal place of business at 300 Third Street, Cambridge, Massachusetts 02142.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.01 per share, of the Company (the "**Common Stock**"), or, if Shareholder Approval is not obtained prior to the date that the conditions to Closing set forth in Section 6, Section 7, and Section 8 have been satisfied or waived as provided therein, certain shares of Series A Redeemable Convertible Preferred Stock, par value $0.01 per share, of the Company (the "**Preferred Stock**"), having the preferences, rights and limitations set forth in the form of Certificate of Designations attached hereto as Exhibit A (the "**Certificate of Designations**").

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**Affiliate**" shall mean, with respect to any Person, another Person which Controls, is Controlled by or is under common Control with such Person. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

"**Agreement**" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

"**Business Day**" shall mean a day on which commercial banking institutions in New York, New York are open for business.

"**Collaboration Agreement**" shall mean the Master Agreement by and between the Investor and the Company, dated as of April 8, 2019.

"**Control**" (including the terms "Controlled by" or "under common Control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to Control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the

right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

"**Controlled Affiliate**" shall mean, with respect to a Person, an Affiliate of such Person Controlled by such Person.

"**Effect**" shall have the meaning set forth in the definition of "Material Adverse Effect."

"**Governmental Authority**" shall mean any court, agency, authority, department or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

"**Intellectual Property**" shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.

"**Intellectual Property License**" shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.

"**Investor Agreement**" shall mean the Investor Agreement by and between the Investor and the Company, dated as of April 8, 2019.

"**Law**" or "**Laws**" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

"**Lien**" shall mean a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"**Material Adverse Effect**" shall mean any change, event or occurrence (each, an "**Effect**") that, individually or when taken together with all other Effects, has (i) a material adverse effect on the business, financial condition, assets, results of operations or prospects of the Company and its subsidiaries, taken as a whole, or (ii) a material adverse effect on the Company's ability to perform its obligations, or consummate the Transaction, in accordance with the terms of this Agreement, except in the case of (i) or (ii) to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof that, in each case, generally affect the biotechnology or biopharmaceutical industries, (C) the announcement of this Agreement or the Collaboration Agreement or the identity of the Investor, (D) any change in the trading prices or trading volume of the Common Stock (it being understood that the facts giving rise to or contributing to any such change may be deemed to constitute, or be taken into account when determining whether there has been or will be, a Material Adverse Effect, except to the extent any of such facts is an Effect referred in clauses (A)

through (I) of this definition), (E) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (F) earthquakes, hurricanes, floods or other natural disasters, (G) any action taken by the Company contemplated by this Agreement or in accordance with the Collaboration Agreement or with the Investor's written consent, (H) any breach, violation or non-performance by the Investor or any of its Controlled Affiliates under the Collaboration Agreement, or (I) shareholder litigation arising out of or in connection with the execution, delivery or performance of the Transaction Agreements; provided, that, with respect to clauses (A), (B), (E) and (F), such Effect does not have a materially disproportionate and adverse effect on the Company relative to other companies in the biotechnology or biopharmaceutical industries.

"**Organizational Documents**" shall mean (i) the Restated Certificate of Incorporation of the Company dated as of June 3, 2004, as amended through the date of this Agreement and (ii) the Amended and Restated Bylaws of the Company, as amended through the date of this Agreement.

"**Per Share Purchase Price**" shall mean (i) if Common Stock is issued and sold hereunder, $90.00, or (ii) if Preferred Stock is issued and sold hereunder, $270.00.

"**Person**" shall mean any individual, partnership, limited liability company, firm, corporation, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"**Shareholder Approval**" shall mean the approval of the Company's shareholders to amend the Company's Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock by at least the number of shares of Common Stock equal to the number of shares of Common Stock issuable hereunder.

"**Termination Date**" shall mean September 30, 2019.

"**Third Party**" shall mean any Person (other than a Governmental Authority) other than the Investor, the Company or any Affiliate of the Investor or the Company.

"**Transaction**" shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"**Transaction Agreements**" shall mean this Agreement, the Investor Agreement and the Collaboration Agreement.

1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Aggregate Purchase Price	Section 2
Certificate of Designations	Preamble
Closing	Section 3.1
Closing Date	Section 3.1
Common Stock	Preamble
Company	Preamble
Company SEC Documents	Section 4.11(a)
DOJ	Section 10.2(a)
Exchange Act	Section 4.11(a)
FTC	Section 10.2(a)
HSR Act	Section 4.7
Investor	Preamble
LAS	Section 4.7
Modified Clause	Section 11.7
Permits	Section 4.10
Preferred Stock	Preamble
SEC	Section 4.7
Securities Act	Section 4.11(a)
Shares	Section 2
Subsidiaries	Section 4.3

2. Purchase and Sale of Common Stock or Preferred Stock. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor, free and clear of all liens, other than any liens arising as a result of any action by the Investor, and the Investor shall purchase from the Company, a number of shares of Common Stock, or, if Shareholder Approval is not obtained prior to the date that the conditions to Closing set forth in Section 6, Section 7, and Section 8 have been

satisfied or waived as provided therein, a number of shares of Preferred Stock (such shares of Common Stock or Preferred Stock, as applicable, the "**Shares**") equal to the amount obtained by dividing the aggregate purchase price of

$400,000,000.00 (the "**Aggregate Purchase Price**") by the Per Share Purchase Price rounded up to the nearest whole share. In the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing which affects or relates to the Common Stock, the number of Shares shall be adjusted proportionately.

3. Closing Date; Deliveries.

3.1 Closing Date. Subject to the satisfaction or waiver of all the conditions to the Closing set forth in Sections 6, 7 and 8 hereof, the closing of the purchase and sale of the Shares hereunder (the "**Closing**") shall be held on the third (3rd) Business Day after the satisfaction of the conditions to Closing set forth in Sections 6, 7 and 8 (other than those conditions that by their nature are to be satisfied at the Closing), at 10:00 a.m. Boston time, at the offices of Goodwin Procter LLP, 100 Northern Avenue, Boston, Massachusetts 02210, or at such other time, date and location as the parties may agree in writing; provided, that in no event shall the Closing occur prior to the second Business Day following the 2019 annual meeting of stockholders of the Company. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

3.2 Deliveries.

(a) Deliveries by the Company. At the Closing, the Company shall instruct its transfer agent to register the Shares in book-entry in the name of the Investor and shall cause the transfer agent to deliver written confirmation of the book-entry delivery of the Shares to the Investor. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6 and 8.3(b) of this Agreement have been fulfilled; (ii) a certificate of the secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated Bylaws of the Company as in effect on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; and (C) that attached thereto is a true and complete copy of the Company's Restated Certificate of Incorporation, including the Certificate of Designations, if applicable, as in effect on the Closing Date; and (iii) a legal opinion of Goodwin Proctor LLP, counsel to the Company, in form and substance reasonably acceptable to the Investor.

(b) Deliveries by the Investor. At the Closing, the Investor shall deliver to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than five (5) Business Days before the Closing Date.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:

4.1 Organization, Good Standing and Qualification.

(a) Each of the Company and the Subsidiaries (as defined below) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Each of the Company and the Subsidiaries has all requisite corporate power and corporate authority to own, lease and operate its properties and assets, to carry on its business as now conducted, and as proposed to be conducted as described in the Company SEC Documents, and the Company has all requisite corporate power to enter into the Transaction Agreements to issue and sell the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

(b) Each of the Company and its Subsidiaries the qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by the Company or Subsidiary, as applicable, or the nature of the business conducted by the Company or Subsidiary, as applicable, makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

4.2 Capitalization and Voting Rights.

(a) The authorized capital of the Company as of the date hereof consists of: (i) 125,000,000 shares of Common Stock of which, as of the date of this Agreement, 106,437,145 shares are issued and outstanding and (ii) 5,000,000 shares of preferred stock, par value $0.01 per share, none of which are issued and outstanding as of the date of this Agreement. All of the issued and outstanding shares of Common Stock (A) have been duly authorized and validly issued, (B) are fully paid and non-assessable and (C) were issued in compliance with all applicable federal and state securities Laws.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(c) Except as described or referred to in Section 4.2(a) above, as provided in the Investor Agreement and as set forth in the Company SEC Documents, as of the date hereof, there are not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company or (ii) except as set forth in the Investor Agreement, any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.

(d) Except as provided in the Investor Agreement and as set forth in the Company SEC Documents, the Company is not a party to or subject to any agreement or

understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.

(e) Except as provided in the Investor Agreement and as set forth in the Company's filings with the SEC, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.

(f) The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration.

4.3 Subsidiaries. The Company has disclosed all of its subsidiaries required to be disclosed pursuant to Item 601(b)(21) of Regulation S-K in an exhibit to its Annual Report on Form 10-K (the "**Subsidiaries**"). The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

4.4 Authorization.

(a) Subject to the Company's receipt of the Shareholder Approval in the event that Common Stock is issued and sold hereunder, all requisite corporate action on the part of the Company, its directors and stockholders required by applicable Law for the authorization, execution and delivery by the Company of the Transaction Agreements and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken;

(b) Each of this Agreement and the Investor Agreement has been duly executed and delivered by the Company, and upon the due execution and delivery thereof by the Investor will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

(c) No stop order or suspension of trading of the Common Stock has been imposed by Nasdaq, the SEC or any other Governmental Authority and remains in effect.

4.5 No Defaults. The Company is not in default under or in violation of (a) its Organizational Documents, (b) any provision of applicable Law or any ruling, writ, injunction, order, Permit, judgment or decree of any Governmental Authority or (c) any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound, except, in the case of subsections (b) and (c), as would not have a Material Adverse

Effect. There exists no condition, event or act which after notice, lapse of time, or both, would constitute a default or violation by the Company under any of the foregoing, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect.

4.6 No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Company do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound (c) violate or conflict with any of the provisions of the Company's Organizational Documents or (d) result in any encumbrance upon any of the Shares, other than restrictions pursuant to the Investor Agreement or securities Laws, or any of the properties or assets of the Company or any Subsidiary, except, in the case of subsections (a) and (b), as would not have a Material Adverse Effect.

4.7 No Governmental Authority or Third-Party Consents. No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by the Company in connection with the authorization, execution and delivery by the Company of any of the Transaction Agreements or with the authorization, issue and sale by the Company of the Shares, except (i) such filings as may be required to be made with the Securities and Exchange Commission (the "**SEC**") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**") and (iii) if required, with respect to the Shares, the filing with The Nasdaq Stock Market LLC of, and the absence of unresolved issues with respect to, a Notification Form: Listing of Additional Shares (the "**LAS**").

4.8 Valid Issuance of Shares. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.

4.9 Litigation. Except as set forth in the Company SEC Documents filed prior to the date of this Agreement, there is no action, suit, proceeding or investigation pending (of which the Company has received notice or otherwise has knowledge) or, to the Company's knowledge, threatened, against the Company or which the Company intends to initiate which has had or is reasonably likely to have a Material Adverse Effect.

4.10 Licenses and Other Rights; Compliance with Laws. The Company has all franchises, permits, licenses and other rights and privileges ("**Permits**") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a Material

Adverse Effect. The Company has not taken any action that would interfere with the Company's ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have a Material Adverse Effect. The Company is and has been in compliance with all Laws applicable to its business, properties and assets, and to the products and services sold by it, except where the failure to be in compliance does not and would not have a Material Adverse Effect.

4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market.

(a) Since December 31, 2016, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein), and any required amendments to any of the foregoing, with the SEC (the "**Company SEC Documents**"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act of 1933, as amended (the "**Securities Act**"), and the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in its quarterly reports on Form 10-Q for the quarterly periods ended September 30, 2018, June 30, 2018, and March 31, 2018 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the Company SEC Documents or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the Company SEC Documents, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not, individually or in the aggregate, have a Material Adverse Effect.

(c) As of the date of this Agreement, the Common Stock is listed on The Nasdaq Global Select Market, and the Company has taken no action designed to, or which is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from The Nasdaq Global Select Market. As of the date of this Agreement, the Company has not received any notification that, and has no knowledge that, the SEC or The Nasdaq Stock Market LLC is contemplating terminating such listing or registration.

4.12 Absence of Certain Changes. Except as disclosed in the Company SEC Documents, since December 31, 2018, there has not occurred any event that has caused or would reasonably be expected to cause a Material Adverse Effect.

4.13 Internal Controls; Disclosure Controls and Procedures. The Company maintains internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The Company has implemented the "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) required in order for the Principal Executive Officer and Principal Financial Officer of the Company to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects. Each of the Principal Executive Officer and the Principal Financial Officer of the Company (or each former Principal Executive Officer of the Company and each former Principal Financial Officer of the Company, as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC.

4.14 Intellectual Property. The Intellectual Property that is owned by the Company is owned free from any liens or restrictions, and all of the Company's material Intellectual Property Licenses are in full force and effect in accordance with their terms and are free of any liens or restrictions except (a) where the failure to be free from such liens or restrictions would not have a Material Adverse Effect or (b) as set forth in any such Intellectual Property License. Except as set forth in the Company SEC Documents, there is no legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise has knowledge) or, to the knowledge of the Company, threatened, (i) challenging the right of the Company in respect of any Company Intellectual Property, or (ii) that claims that any default exists under any Intellectual Property License, except, in the case of (i) and (ii) above, where any such claim, demand or proceeding would not have a Material Adverse Effect.

4.15 Offering. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9 and 5.10, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.

4.16 No Integration. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

4.17 Brokers' or Finders' Fees. No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission from the Company in connection with the transactions contemplated by the Transaction Agreements.

4.18 Not Investment Company. The Company is not, and immediately after receipt of the Aggregate Purchase Price will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

4.19 Insurance. The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company is engaged and for an enterprise at a substantially similar stage of lifecycle as the Company, including, but not limited to, directors and officers insurance coverage. To the Company's knowledge, it will be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business.

4.20 No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) in a manner or under any circumstances that would require the registration of the Shares under the Securities Act (including, without limitation, by virtue of the integration of the offering of the Shares with any prior offering of Company shares).

4.21 Foreign Corrupt Practices. Neither the Company, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of Law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.

4.22 Regulation M Compliance. The Company has not taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares.

4.23 Office of Foreign Assets Control. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

4.24 U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Investor's request.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company, that:

5.1 Organization; Good Standing. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. The Investor has or will have all requisite power and authority to enter into the Transaction Agreements, to purchase the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

5.2 Authorization. All requisite action on the part of the Investor and its directors and stockholders, required by applicable Law for the authorization, execution and delivery by the Investor of the Transaction Agreements and the performance of all of its obligations thereunder, including the subscription for and purchase of the Shares, has been taken. Each of this Agreement and the Investor Agreement has been duly executed and delivered by the Investor and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms (except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (b) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

5.3 No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Investor do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Investor or any of its assets, are bound, or (c) violate or conflict with any of the provisions of the Investor's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents), except as would not impair or adversely affect the ability of the Investor to consummate the Transactions and perform its obligations under the Transaction Agreements and except, in the case of subsections (a) and (b), as would not have a Material Adverse Effect on the Investor.

5.4 No Governmental Authority or Third-Party Consents. No consent, approval, authorization or other order of any Governmental Authority or other Third Party is required to be obtained by the Investor in connection with the authorization, execution and delivery of any of the Transaction Agreements or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.

5.5 Purchase Entirely for Own Account. The Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Shares.

5.6 Disclosure of Information. The Investor has received all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

5.7 Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

5.8 Acquiring Person. As of the date of this Agreement and immediately prior to the Closing, neither the Investor nor any of its Controlled Affiliates beneficially owns, or will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership), any securities of the Company.

5.9 Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144 of the Securities Act, as presently in effect.

5.10 Legends. The Investor understands that the Shares in book-entry form shall be subject to the following legends:

(a) "These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to Alnylam Pharmaceuticals, Inc.) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act."; and

(b) "The securities represented by this certificate are subject to and shall be transferable only upon the terms and conditions of an Investor Agreement by and between Alnylam Pharmaceuticals, Inc. and Regeneron Pharmaceuticals, Inc., a copy of which is on file with the Secretary of Alnylam Pharmaceuticals, Inc."

5.11 Financial Assurances. As of the date hereof and as of the Closing Date, the Investor has and will have access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.

6. Investor's Conditions to Closing. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):

6.1 Representations and Warranties. The representations and warranties made by the Company in Section 4 hereof shall be true and correct (i) as of the date of this Agreement and (ii) as of the Closing Date as though made on and as of the Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.1, all such representations and warranties of the Company (other than Sections 4.1(a), 4.2, 4.3, 4.4, 4.8, 4.15, 4.16 and 4.20 of this Agreement) shall be deemed to be true and correct for purposes of this Section 6.1 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein (other than any reference to "material" in Sections 4.11(a) and 4.11(b)), individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect; provided further, however, that the representations made by the Company in Section 4.2(a) shall be updated by the Company and delivered to the Investor prior to Closing such that the Section 4.2(a) shall be true and correct as of the Closing Date as though made on and as of the Closing Date.

6.2 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

6.3 Investor Agreement. The Company shall have duly executed and delivered to the Investor the Investor Agreement, and there shall have been no termination of the Investor Agreement that, as of the Closing, is effective.

6.4 Collaboration Agreement. The Company shall have duly executed and delivered to the Investor the Collaboration Agreement, and there shall have been no termination of the Collaboration Agreement that, as of the Closing, is effective.

6.5 No Material Adverse Effect. From and after the date of this Agreement until the Closing Date, there shall have occurred no event that has caused or would reasonably be expected to cause a Material Adverse Effect.

6.6 Restated Certificate or Certificate of Designations. If Shareholder Approval is obtained prior to the date that the conditions to Closing set forth in this Section 6, Section 7, and Section 8 have been satisfied or waived as provided herein and therein, the Company shall have filed a Certificate of Amendment to the Restated Certificate of Incorporation of the Company with the Secretary of State of the State of Delaware prior to the Closing to increase the number of authorized shares of Common Stock by at least the number of shares of Common Stock equal to the number of Shares of Common Stock issuable hereunder, which such Certificate of Amendment to the Restated Certificate of Incorporation shall continue to be in full force and effect as of the Closing. If Shareholder Approval is not obtained prior to the date that the conditions to Closing set forth in this Section 6, Section 7, and Section 8 have

been satisfied or waived as provided herein and therein, the Company shall have filed the Certificate of Designations with the Secretary of State of the State of Delaware prior to the Closing, which such Certificate of Designations shall continue to be in full force and effect as of the Closing.

7. Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):

7.1 Representations and Warranties. The representations and warranties made by the Investor in Section 5 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of the Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date.

7.2 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.

7.3 Investor Agreement. The Investor shall have duly executed and delivered to the Company the Investor Agreement, and there shall have been no termination of the Investor Agreement that, as of the Closing, is effective.

7.4 Collaboration Agreement. The Investor shall have duly executed and delivered to the Company the Collaboration Agreement, and there shall have been no termination of the Collaboration Agreement that, as of the Closing, is effective.

8. Mutual Conditions to Closing. The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:

8.1 HSR Act and Other Qualifications. The filings required under the HSR Act in connection with the Transaction Agreements, as applicable, shall have been made and the required waiting period shall have expired or been terminated as of the Closing Date, and all other authorizations, consents, waivers, permits, approvals, qualifications and registrations to be obtained or effected with any Governmental Authority, including, without limitation, necessary blue sky permits and qualifications required by any state for the offer and sale to the Investor of the Shares, shall have been obtained and shall be in effect as of the Closing Date.

8.2 Injunctions. There shall be no Law, injunction (whether temporary, preliminary or permanent), judgment or ruling enacted, promulgated, issued, entered, amended or enforced by any Governmental Authority in effect enjoining, restraining, preventing or prohibiting the consummation of the transactions contemplated by any Transaction Agreement or making the consummation of the transactions contemplated by any Transaction Agreement illegal.

8.3 Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company or the Investor that questions the validity of any of the Transaction Agreements, the right of the Company or the Investor to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or which, if determined adversely, would impose substantial monetary damages on the Company or the Investor as a result of the consummation of the transactions contemplated by any Transaction Agreement.

8.4 No Prohibition; Market Listing. (a) No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect; and (b) the Common Stock shall be eligible for listing on The Nasdaq Global Select Market.

9. Termination.

9.1 Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and the Investor;

(b) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party; provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

(c) the Investor, if (i) any of the representations and warranties of the Company contained in Section 4 of this Agreement shall fail to be true and correct, (ii) there shall be a breach by the Company of any covenant of the Company in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Sections 6 or 8, and (B) which is not curable or, if curable, is not cured on or prior to the twentieth (20th) day after written notice thereof is given by the Investor to the Company, or (iii) the Closing Date shall not have occurred by the Termination Date; or

(d) the Company, if (i) any of the representations and warranties of the Investor contained in Section 5 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by the Investor of any covenant of the Investor in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 7 or 8, and (B) which is not curable or, if curable, is not cured on or prior to the twentieth (20th) day after written notice thereof is given the Company to the Investor.

9.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 9.1 hereof, (a) this Agreement (except for this Section 9.2 and Section 11 hereof (other than Section 11.13), and any definitions set forth in this Agreement and used in

such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 9.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

10. Additional Covenants and Agreements.

10.1 Market Listing. From the date hereof through the Closing Date, Company shall use all reasonable efforts to (a) maintain the listing and trading of the Common Stock on The Nasdaq Global Select Market and (b) effect the listing of the Shares on The Nasdaq Global Select Market, including submitting the LAS to The Nasdaq Stock Market LLC, if required.

10.2 Notification under the HSR Act.

(a) Filing. The Investor and the Company shall use best efforts, as promptly as practicable, but in no event later than seven (7) Business Days following the execution and delivery of this Agreement, to file or cause to be filed with the United States Federal Trade Commission (the "**FTC**") and the United States Department of Justice (the "**DOJ**"), the notification and report form required for the transactions contemplated hereby and any supplemental information requested in connection therewith pursuant to the HSR Act, which forms shall specifically request early termination of the waiting period prescribed by the HSR Act. Each of the Investor and the Company shall furnish to each other's counsel such necessary information and reasonable assistance as the other may request in connection with its preparation of any filing or submission that is necessary under the HSR Act. Each of the Investor and the Company shall be responsible for their own costs and expenses, and the Investor and the Company each shall pay one-half of the filing fee required under the HSR Act.

(b) Clearance. The Investor and the Company shall use reasonable best efforts to promptly obtain clearance under the HSR Act for the consummation of this Agreement. The Investor and the Company each agree not to take any action that will have the effect of delaying, impairing, or impeding, the early termination or expiration of the applicable waiting period under the HSR Act for the transactions contemplated by this Agreement. The Investor and the Company commit to instruct their respective counsel to cooperate with each other and use reasonable best efforts to facilitate and expedite the identification and resolution of any issues arising under the HSR Act and, consequently, the expiration or termination of the applicable HSR Act waiting period at the earliest practicable date. Such reasonable best efforts and cooperation include, but are not limited to, counsel's undertaking (a) to promptly inform the other party of any written or oral communication received from the DOJ or the FTC; (b) to respond as promptly as practicable to any request from the DOJ or FTC for information, documents or other materials in connection with a review of the transactions contemplated by this Agreement; (c) to provide to the other party, and permit the other party to review and comment in advance of submission, all proposed correspondence, filings, and written communications to the DOJ or FTC with respect to the transactions contemplated by this

Agreement; and (d) not to participate in any substantive meeting or discussion with the DOJ or the FTC in respect of an investigation or inquiry concerning the transactions contemplated by this Agreement unless it consults with the other party in advance and, except as prohibited by applicable law or the DOJ or the FTC, gives the other party the opportunity to attend and participate therein. The parties will consider in good faith the views of one another, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions, and proposals made or submitted by or on behalf of any party to the DOJ or the FTC, except as may be prohibited by or restricted by law.

10.3 Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to: (a) cause the conditions precedent set forth in Sections 6, 7 and 8 to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from the Nasdaq Stock Market LLC with respect to the LAS); (b) obtain all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and make all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any); and (c) obtain all necessary consents, approvals or waivers from Third Parties.

10.4 Effect of Waiver of Condition to Closing. In the event that, as of the Closing, the Investor provides written notice to the Company of its waiver of the condition regarding a Material Adverse Effect set forth in Section 6.5 of this Agreement, the Investor shall be deemed to have waived any right of recourse against the Company for, and agreed not to sue the Company in respect of, any and all events or inaccuracies in any representations or warranties of the Company (a) that, as of the Closing, have caused or would reasonably be expected to cause such Material Adverse Effect and (b) of which the Investor had notice in writing from the Company immediately prior to the Closing.

10.5 Nasdaq Matters. Prior to the Closing, the Company shall comply in all material respects with all listing, reporting, filing, and other obligations under the rules of Nasdaq.

10.6 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in the Securities Act) that would be integrated with the offer or sale of the Shares to be issued to the Investor hereunder for purposes of the rules and regulations of any of the following markets or exchanges on which the Common Stock of the Company is listed or quoted for trading on the date in question: the Pink OTC Markets, the OTC Bulletin Board, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the NYSE American or the New York Stock Exchange.

10.7 Blue Sky Filings. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the

Shares for, sale to the Investor at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Investor.

10.8 Legend Removal. After the expiration of the Lock-up Term (as defined in the Investor Agreement), the Company shall cause the legends set forth in Section 5.10(a) and (b) to be removed from the Shares, no later than three (3) Business Days from receipt of a request from the Investor pursuant to this Section 10.8, if (i) the Shares have been resold under an effective registration statement under the Securities Act, (ii) the Shares have been or will be transferred in compliance with Rule 144 under the Securities Act, (iii) the Shares are eligible for resale pursuant to Rule 144(b)(1)(i) under the Securities Act without the requirement for the Company to be in compliance with the current public information required under Rule 144 under the Securities Act as to such Shares and without volume or manner-of-sale restrictions or (iv) the Investor shall have provided the Company with an opinion of counsel, reasonably satisfactory to the Company, stating that such securities may lawfully be transferred without registration under the Securities Act (assuming for this purpose that the Investor is not an affiliate of the Issuer).

10.9 Annual Meeting. The Company agrees to use its reasonable best efforts to, at the next regularly scheduled annual meeting of stockholders of the Company, which annual meeting shall in no event occur later than May 10, 2019, obtain the Shareholder Approval. If the Shareholder Approval is not obtained at the 2019 annual meeting of stockholders of the Company, the Company shall use its commercially reasonable efforts to obtain the Shareholder Approval as soon as practicable thereafter.

11. Miscellaneous.

11.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 11.3 or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

11.2 Waiver. Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party.

No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

11.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

11.4 Entire Agreement. This Agreement, the Collaboration Agreement and the Investor Agreement contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

11.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company.

11.6 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

11.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

11.8 Assignment. Neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (a) the prior written consent of the Company in the case of any assignment by the Investor or (b) the prior written consent of the Investor in the case of an assignment by the Company.

11.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

11.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

11.11 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto, except with respect to a Permitted Transferee (as defined in the Investor Agreement). No Third Party (other than a Permitted Transferee) shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

11.12 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

11.13 Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing for eighteen (18) months, except for (a) the representations and warranties set forth in Sections 4.1, 4.2, 4.4, 4.5(a), 4.6(c), 4.8, 4.13, 4.14, 4.15, 4.16, 4.17, 5.1, 5.2, 5.5, 5.7, 5.8, 5.9 and 5.10, which shall survive the Closing and (b) the representation and warranty of the Investor in Section 5.11, which shall not survive the Closing. The parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

11.14 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

11.15 Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

(*Signature Page Follows*)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Nouhad Husseini
Name: Nouhad Husseini
Title: Vice President

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ John M. Maraganore, Ph.D.
Name: John M. Maraganore, Ph.D.
Title: Chief Executive Officer

EXHIBIT A

FORM OF CERTIFICATE OF DESIGNATIONS

ALNYLAM PHARMACEUTICALS, INC.

CERTIFICATE OF DESIGNATIONS OF PREFERENCES,

RIGHTS AND LIMITATIONS

OF

SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK

PURSUANT TO SECTION 151 OF THE
DELAWARE GENERAL CORPORATION LAW

The undersigned, John Maraganore, does hereby certify that:

1. He is the Chief Executive Officer of Alnylam Pharmaceuticals, Inc., a Delaware corporation (the "Corporation").

2. The Corporation is authorized to issue Five Million shares of Preferred Stock, $.01 par value, none of which have been issued.

3. The following resolutions were duly adopted by the board of directors of the Corporation (the "Board of Directors"):

WHEREAS, the certificate of incorporation of the Corporation provides for a class of its authorized stock known as Preferred Stock, consisting of Five Million shares, $.01 par value per share, issuable from time to time in one or more series;

WHEREAS, the Board of Directors is authorized to fix the dividend rights, dividend rate, voting rights, conversion rights, rights and terms of redemption and liquidation preferences of any wholly unissued series of Preferred Stock and the number of shares constituting any series and the designation thereof, of any of them; and

WHEREAS, it is the desire of the Board of Directors, pursuant to its authority as aforesaid, to fix the rights, preferences, restrictions and other matters relating to a series of the Preferred Stock, which shall consist of up to one million six hundred thousand (1,600,000) shares of the Preferred Stock which the Corporation has the authority to issue, as follows:

NOW, THEREFORE, BE IT RESOLVED, that the Board of Directors does hereby provide for the issuance of a series of Preferred Stock for cash or exchange of other securities, rights or property and does hereby fix and determine the rights, preferences, restrictions and other matters relating to such series of Preferred Stock as follows:

TERMS OF PREFERRED STOCK

1. Definitions. For purposes hereof, the following terms shall have the following meanings:

"Affiliate" has the meaning set forth in the Purchase Agreement.

"Business Day" means a day on which commercial banking institutions in New York, New York are open for business.

"Charter Amendment" means the amendment of the Corporation's Restated Certificate of Incorporation, as amended, to increase the authorized number of shares of Common Stock to not less than 175,000,000.

"Common Stock" means the Corporation's common stock, par value $.01 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Corporation which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Investor Agreement" means the Investor Agreement, dated as of April [•], 2019, by and between the Corporation and the original holder of Series A Preferred Stock, as amended, modified or supplemented from time to time in accordance with its terms.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Purchase Agreement" means the Stock Purchase Agreement, dated as of April [•], 2019, by and between the Corporation and the original holder of Series A Preferred Stock, as amended, modified or supplemented from time to time in accordance with its terms.

"Stockholder Approval" means the approval of the Charter Amendment by the requisite stockholders of the Corporation.

"Transaction Documents" means this Certificate of Designations, the Purchase Agreement, and all exhibits and schedules hereto and thereto.

"Transfer Agent" means Computershare Trust Company, N.A., the current transfer agent of the Corporation, and any successor transfer agent of the Corporation.

2. Designation, Amount and Par Value. The series of Preferred Stock shall be designated as its Series A Redeemable Convertible Preferred Stock (the "Series A Preferred Stock"), and the number of shares so designated shall be up to one million six hundred thousand (1,600,000) (which shall not be subject to increase without the written consent of all of the holders of the Series A Preferred Stock (each, a "Holder" and collectively, the "Holders")). Each share of Series A Preferred Stock shall have a par value of $.01 per share and a stated value equal to $3.00 (the "Stated Value").

3. Dividends. Except for stock dividends or distributions for which adjustments are to be made pursuant to Section 7, Holders shall be entitled to receive, and the Corporation shall pay, dividends or distributions on shares of Series A Preferred Stock equal (on an as-if-converted-to-Common Stock basis) to and in the same form as dividends or distributions actually paid on shares of the Common Stock when, as and if such dividends or distributions are paid on shares of the Common Stock. No other dividends or distributions shall be paid on shares of Series A Preferred Stock.

4. Liquidation, Dissolution or Winding Up.

4.1 Preferential Payments to Holders of Series A Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation (a "Liquidation"), the Holders shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to such amount per share as would have been payable had all shares of Series A Preferred Stock been converted into Common Stock pursuant to Section 6 immediately prior to such Liquidation. The Corporation will mail written notice of any such Liquidation, not less than 30 days prior to the payment date stated therein, to each Holder. If upon any such Liquidation, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the Holders the full amount to which they shall be entitled under this Section 4.1, the Holders shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. For the avoidance of doubt, neither the sale, conveyance, exchange or transfer (for cash, shares of stock, securities or other consideration) of all or substantially all of the property or assets of the Corporation nor the consolidation or merger of the Corporation with or into one or more other entities shall be deemed, in and of itself, to be a Liquidation.

4.2 Payments to Holders of Common Stock. In the event of any Liquidation, after the payment of all preferential amounts required to be paid to the Holders pursuant to Section 4.1, the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares held by each such holder, subject to the terms of other series of preferred stock of the Corporation, if any, outstanding as of such Liquidation.

5. Voting. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each Holder shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Series A Preferred Stock held by such Holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the provisions of the Certificate of Incorporation, Holders shall vote together with the holders of Common Stock as a single class.

6. Conversion.

6.1 Mandatory, Automatic Conversion. Upon the filing and acceptance of the Charter Amendment with the Secretary of State of the State of Delaware, each share of Series

A Preferred Stock shall automatically convert into that number of shares of Common Stock determined by dividing the Stated Value of such share of Series A Preferred Stock by the Conversion Price (such ratio, the "Conversion Ratio"). Any conversion pursuant to this Section 6.1 shall occur automatically and without any further action by the Holders and whether or not the certificates representing such shares of Series A Preferred Stock are surrendered to the Corporation or its Transfer Agent. Upon the occurrence of such automatic conversion, the Corporation shall provide written notice to the Holders, and the Holders shall, a reasonable time thereafter, surrender the certificates representing such shares at the office of the Corporation or any Transfer Agent for the Series A Preferred Stock. Thereupon, there shall be issued and delivered to such Holder promptly at such office and in its name as shown on the Corporation's stock records, a certificate or certificates for the number of shares of Common Stock into which the shares of Series A Preferred Stock surrendered were convertible on the date on which such automatic conversion occurred. Notwithstanding anything to the contrary herein, any shares of Common Stock issued upon conversion of Series A Preferred Stock will be in uncertificated, book entry form as permitted by the bylaws of the Corporation and Delaware law. Within a reasonable time after the issuance or transfer of uncertificated shares, the Corporation shall, or shall cause the Transfer Agent to, send to the registered owner thereof a notice of ownership of capital stock of the Corporation containing the information required to be set forth or stated on certificates pursuant to Delaware Law.

6.2 Conversion Price. The conversion price for the Series A Preferred Stock (the "Conversion Price") shall equal $1.00, subject to adjustment as provided in Section 7.

6.3 Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of the Series A Preferred Stock. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such conversion, the Corporation shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share.

6.4 Transfer Taxes and Expenses. The issuance of certificates for shares of the Common Stock on conversion of Series A Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such certificates; provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such certificate upon conversion in a name other than that of the Holders of such shares of Series A Preferred Stock and the Corporation shall not be required to issue or deliver such certificates unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid.

6.5 Issuance Limitations. Notwithstanding anything herein to the contrary, the Series A Preferred Stock may not be converted into any shares of Common Stock unless the Corporation has obtained the Stockholder Approval.

7. Certain Adjustments.

7.1 Stock Dividends and Stock Splits. If the Corporation, at any time while the Series A Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock on shares of Common Stock or any other Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of, or payment of a dividend on, Series A Preferred Stock), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Corporation, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section 7.1 shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

7.2 Pro Rata Distributions. During such time as Series A Preferred Stock is outstanding, if the Corporation declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of the Series A Preferred Stock, then, in each such case, Holders shall be entitled to participate in such Distribution to the same extent that such Holders would have participated therein if such Holders had held the number of shares of Common Stock acquirable upon complete conversion of Series A Preferred Stock immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution.

7.3 Fundamental Transaction. If, at any time while Series A Preferred Stock is outstanding, (i) the Corporation, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Corporation with or into another Person (except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation), (ii) the Corporation, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Corporation, directly or indirectly, in one or more

related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Corporation, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or Affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then upon the consummation of such Fundamental Transaction each share of Series A Preferred Stock shall be converted into the right to receive the amount and type of consideration that would have been issuable had the conversion of the shares of Series A Preferred Stock to Common Stock pursuant to Section 6 occurred immediately prior to the consummation of such Fundamental Transaction (without regard to any limitation in Section 6.5 on the conversion of Series A Preferred Stock).

7.4 Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

7.5 Notice to the Holders of Adjustment to Conversion Price. Whenever the Conversion Price is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder a notice setting forth the Conversion Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

8. Redemption.

8.1 General. The Series A Preferred Stock may not be redeemed by the Corporation pursuant to Section 8.3 until the expiration or termination of the Lock-Up Term (as defined in the Investor Agreement) (the "Redemption Eligibility Date"); provided, however, that upon a transfer by any Holder of shares of Series A Preferred Stock to any party that is not an Affiliate of such Holder, the Redemption Eligibility Date shall automatically become the four-year anniversary of the Closing Date (as defined in the Purchase Agreement). After the Redemption Eligibility Date, the Series A Preferred Stock shall be redeemed by the Corporation upon the election of the Holders as provided in this Section 8.

8.2 Redemption at Election of the Holders. Unless prohibited by Delaware law governing distributions to stockholders, on or after the Redemption Eligibility Date, each share of Series A Preferred Stock shall be redeemed by the Corporation at a price equal to the product of the Conversion Ratio multiplied by the volume-weighted average price of the Common Stock for the fifteen trading days prior to the date of the Redemption Request (the "Redemption Price"), such redemption to be effected not more than one month after receipt by the Corporation, at any time on or after the Redemption Eligibility Date, from the Holders of all of the then outstanding shares of Series A Preferred Stock of written notice requesting redemption of all shares of Series A Preferred Stock (the "Redemption Request").

8.3 Redemption. The date on which the redemption is effected shall be referred to as a "Redemption Date." On the Redemption Date, the Corporation shall redeem the number of outstanding shares of Series A Preferred Stock set forth in the Redemption Request on a pro rata basis in accordance with the number of shares of Series A Preferred Stock owned by each Holder thereof. After receipt of the Redemption Request and prior to the Redemption Date, the Corporation shall take all actions required or permitted under Delaware law to permit the redemption and to make funds legally available for such redemption. To the extent that the Corporation has insufficient funds to redeem all of the shares of Series A Preferred Stock to be redeemed, the Corporation shall ratably redeem the maximum number of shares that it may redeem consistent with such law, and shall redeem the remaining shares as soon as reasonably practicable following the date on which it may lawfully do so under such law. Following the receipt of the Redemption Request, the Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation prior to fully redeeming the number of outstanding shares of Series A Preferred Stock set forth in the Redemption Request.

8.4 Surrender of Certificates; Payment. On or before the Redemption Date, each Holder shall surrender the certificate or certificates representing the shares of Series A Preferred Stock owned by each such Holder (or, if such registered Holder alleges that such certificate has been lost, stolen or destroyed, evidence of such loss, theft or destruction of such certificate reasonably satisfactory to the Corporation) to the Corporation, in the manner and at the place designated by the Corporation, and thereupon the Redemption Price for such shares shall be payable to the order of the Person whose name appears on such certificate or certificates as the owner thereof.

8.5 Rights Subsequent to Redemption. If on the applicable Redemption Date the Redemption Price payable upon redemption of the shares of Series A Preferred Stock to be redeemed on such Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that the certificates evidencing any of the shares of Series A Preferred Stock so called for redemption shall not have been surrendered, no dividends having a record date occurring after the Redemption Date shall be paid in respect of such shares of Series A Preferred Stock and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the Holders to receive the Redemption Price without interest upon surrender of their certificate or certificates therefor.

9. Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth in the Purchase Agreement or, if a Holder's address is not set forth in the Purchase Agreement, to the address of such Holder appearing on the books of the Corporation, and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission).

10. Lost or Mutilated Series A Preferred Stock Certificate. If a Holder's Series A Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Series A Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership hereof reasonably satisfactory to the Corporation.

11. Amendment. At any time any shares of Series A Preferred Stock are outstanding, the Certificate of Incorporation and this Certificate of Designations shall not be amended in any manner that would alter or change the powers, preferences or special rights of the Series A Preferred Stock so as to affect them adversely without the affirmative consent of the holders of a majority of the outstanding shares of Series A Preferred Stock, consenting separately as a class.

12. Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designations shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designations or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designations on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designations on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

13. Status of Converted or Redeemed Series A Preferred Stock. Shares of Series A Preferred Stock may only be issued pursuant to the Purchase Agreement. If any shares of Series A Preferred Stock shall be converted, redeemed or reacquired by the Corporation, such shares shall be deemed to be retired and cancelled and shall resume the status of authorized but unissued shares of Preferred Stock and shall no longer be designated as Series A Preferred Stock.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Corporation has caused this Certificate to be signed this [____] day of [_____] 2019.

ALNYLAM PHARMACEUTICALS, INC.

By:
Name:
Title:

:

EXHIBIT B

NOTICES

(a) If to the Investor:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel

with a copy to:

Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02110
Attention: Alan Leeds, Esq.
Email: alan.leeds@morganlewis.com
Bryan Keighery, Esq.
Email: bryan.keighery@morganlewis.com

(b) If to the Company:

Alnylam Pharmaceuticals, Inc.
300 Third Street
Cambridge, Massachusetts 02142
Attention: Legal Department

with a copy to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Mitchell S. Bloom, Esq.
Email: mbloom@goodwinlaw.com
Gregg L. Katz, Esq.
Email: gkatz@goodwinlaw.com

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2019

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert E. Landry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2019

/s/ Robert E. Landry

Robert E. Landry

Executive Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
August 6, 2019

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
August 6, 2019