

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 September 30, 2006

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

(State or other jurisdiction of incorporation or organization)

13-3444607

(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road
Tarrytown, New York

(Address of principal executive offices)

10591-6707

(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of October 31, 2006:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$0.001 par value	2,296,928
Common Stock, \$0.001 par value	55,153,986

REGENERON PHARMACEUTICALS, INC.
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September 30, 2006

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	September 30, 2006	December 31, 2005
ASSETS		
Current assets		
Cash and cash equivalents	\$ 167,662	\$ 184,508
Marketable securities	94,227	114,037
Accounts receivable	7,940	36,521
Prepaid expenses and other current assets	3,920	3,422
Inventory		2,904
Total current assets	<u>273,749</u>	<u>341,392</u>
Marketable securities	27,708	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	51,035	60,535
Other assets	2,694	3,465
Total assets	<u>\$ 355,186</u>	<u>\$ 423,501</u>
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 19,054	\$ 23,337
Deferred revenue, current portion	13,644	17,020
Total current liabilities	<u>32,698</u>	<u>40,357</u>
Deferred revenue	60,015	69,142
Notes payable	200,000	200,000
Total liabilities	<u>292,713</u>	<u>309,499</u>
Commitments and contingencies		
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 - 2,296,928 in 2006 and 2,347,073 in 2005	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 54,784,449 in 2006 and 54,092,268 in 2005	55	54
Additional paid-in capital	719,157	700,011
Unearned compensation		(315)
Accumulated deficit	(656,646)	(585,280)
Accumulated other comprehensive loss	(95)	(470)
Total stockholders' equity	<u>62,473</u>	<u>114,002</u>
Total liabilities and stockholders' equity	<u>\$ 355,186</u>	<u>\$ 423,501</u>

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

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CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended September 30, 2006	2005	Nine months ended September 30 2006	2005
Revenues				
Contract research and development	\$ 11,448	\$ 11,533	\$ 41,026	\$ 38,580
Contract manufacturing	4,176	4,661	12,075	10,189
	<u>15,624</u>	<u>16,194</u>	<u>53,101</u>	<u>48,769</u>
Expenses				
Research and development	34,808	41,116	101,290	117,670
Contract manufacturing	3,054	3,246	7,716	7,412
General and administrative	6,019	6,219	18,264	18,581
	<u>43,881</u>	<u>50,581</u>	<u>127,270</u>	<u>143,663</u>
Loss from operations	<u>(28,257)</u>	<u>(34,387)</u>	<u>(74,169)</u>	<u>(94,894)</u>
Other income (expense)				
Other contract income				30,640
Investment income	3,858	2,746	11,023	7,515
Interest expense	(3,011)	(3,011)	(9,033)	(9,035)
	<u>847</u>	<u>(265)</u>	<u>1,990</u>	<u>29,120</u>
Net loss before cumulative effect of a change in accounting principle	(27,410)	(34,652)	(72,179)	(65,774)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813	
Net loss	<u>\$ (27,410)</u>	<u>\$ (34,652)</u>	<u>\$ (71,366)</u>	<u>\$ (65,774)</u>
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	\$ (0.48)	\$ (0.62)	\$ (1.27)	\$ (1.18)
Cumulative effect of adopting SFAS 123R			0.02	
Net loss	<u>\$ (0.48)</u>	<u>\$ (0.62)</u>	<u>\$ (1.25)</u>	<u>\$ (1.18)</u>
Weighted average shares outstanding, basic and diluted	57,011	55,978	56,884	55,903

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REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the nine months ended September 30, 2006
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount						
Balance, December 31, 2005	2,347	\$ 2	54,092	\$54	\$700,011	\$(315)	\$(585,280)	\$(470)	\$ 114,002	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			523	1	4,882				4,883	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(50)		50							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					13,508				13,508	
Adjustment to reduce unearned compensation upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss							(71,366)		(71,366)	\$(71,366)
Change in net unrealized loss on marketable securities								375	375	375
Balance, September 30, 2006	2,297	\$ 2	54,784	\$55	\$719,157	—	\$(656,646)	\$ (95)	\$ 62,473	\$(70,991)

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

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CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30,	
	2006	2005
Cash flows from operating activities		
Net loss	\$ (71,366)	\$ (65,774)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	11,196	11,624
Non-cash compensation expense	13,542	17,624
Cumulative effect of a change in accounting principle	(813)	
Changes in assets and liabilities		
Decrease in accounts receivable	28,581	32,566
Decrease (increase) in prepaid expenses and other assets	364	(956)
Decrease in inventory	3,524	1,208
Decrease in deferred revenue	(12,503)	(9,398)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(2,753)	2,657
Total adjustments	41,138	55,325
Net cash used in operating activities	<u>(30,228)</u>	<u>(10,449)</u>
Cash flows from investing activities		
Purchases of marketable securities	(252,037)	(91,078)
Sales or maturities of marketable securities	261,749	185,882
Capital expenditures	(1,603)	(4,613)
Net cash provided by investing activities	<u>8,109</u>	<u>90,191</u>
Cash flows from financing activities		
Net proceeds from the issuance of stock	4,883	1,122
Other	390	
Net cash provided by financing activities	<u>5,273</u>	<u>1,122</u>
Net (decrease) increase in cash and cash equivalents	<u>(16,846)</u>	<u>80,864</u>
Cash and cash equivalents at beginning of period	184,508	95,229
Cash and cash equivalents at end of period	<u>\$ 167,662</u>	<u>\$ 176,093</u>

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)***1. Interim Financial Statements**

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”) 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 adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company’s financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed 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, 2005.

2. Per Share Data

The Company’s basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three and nine months ended September 30, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2006	2005
Net loss (Numerator)	\$(27,410)	\$(34,652)
Weighted-average shares, in thousands (Denominator)	57,011	55,978
Basic and diluted net loss per share	\$ (0.48)	\$ (0.62)

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

	Nine Months Ended September 30,	
	2006	2005
Net loss (Numerator)	\$ (71,366)	\$ (65,774)
Weighted-average shares, in thousands (Denominator)	56,884	55,903
Basic and diluted net loss per share	\$ (1.25)	\$ (1.18)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the September 30, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,082	13,236
Weighted average exercise price	\$ 14.35	\$ 14.54
Restricted Stock:		
Weighted average number, in thousands	—	149
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25

	Nine months ended September 30,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,220	13,335
Weighted average exercise price	\$ 14.31	\$ 14.61
Restricted Stock:		
Weighted average number, in thousands	31	188
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. (“SFAS”) 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company’s loss by \$813 and is included in the Company’s operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on the Company’s loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to the Company’s cash flows for these respective periods.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan (“2000 Incentive Plan”), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals,

REGENERON PHARMACEUTICALS, INC.**Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. The 1990 Incentive Plan has expired and there will be no future awards from the 1990 Incentive Plan. The Company has issued Incentive Stock Options ("ISOs") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of September 30, 2006, there were 6,563,402 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At September 30, 2006, there were 13,967,474 stock options outstanding with exercise prices ranging from \$4.83 to \$51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents in January 2005 vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the nine months ended September 30, 2006 is presented in the following table:

	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Intrinsic Value (in thousands)
Stock options outstanding at January 1, 2006	14,719,492		\$14.23	
Stock options granted	280,900		\$14.90	
Stock options exercised	(552,785)		\$ 9.72	
Stock options forfeited	(315,115)		\$10.47	
Stock options expired	(165,018)		\$24.17	
Stock options outstanding at September 30, 2006	<u>13,967,474</u>	6.30	\$14.39	\$59,450
Stock options vested and exercisable	7,087,863	4.89	\$17.79	\$24,221

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

The total intrinsic value of stock options exercised during the first nine months of 2006 and 2005 was \$3,548 and \$220, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") recognized in operating expenses totaled \$4,762 and \$5,439, respectively, which included \$94 and \$65, respectively, of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled \$13,243, which included \$34 previously capitalized in inventory, and \$16,166, respectively. In addition, for the nine months ended September 30, 2005, \$147 of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was \$19,132 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon the Company's products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three and nine months ended September 30, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended September 30, 2006 and 2005 was \$8.30 and \$5.12 per option, respectively. The weighted-average fair value of the options granted during the nine months ended September 30, 2006 and 2005 was \$9.75 and \$5.79 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

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	Three months ended September 30,	
	2006	2005
Expected volatility	65%	70%
Expected lives from grant date	5.5 years	5.0 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.74%	4.00%

	Nine months ended September 30,	
	2006	2005
Expected volatility	67%	75%
Expected lives from grant date	6.5 years	6.2 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.76%	3.96%

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the nine months ended September 30, 2006 is presented in the following table:

	Number Of Shares	Weighted Average Grant Date Fair Value
Restricted stock outstanding as of January 1, 2006	95,188	\$ 11.16
Restricted stock released	(93,485)	\$ 11.18
Restricted stock forfeited	(1,703)	\$ 9.74
Restricted stock outstanding as of September 30, 2006	<u>—</u>	

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the nine months ended September 30, 2006. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation was combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

For the three months ended September 30 2005, the Company recognized compensation expense related to Restricted Stock awards of \$482. For the nine months ended September 30, 2006 and 2005, the Company recognized compensation expense

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

related to Restricted Stock awards of \$299 and \$1,458, respectively. As of September 30, 2006, there were no unvested shares of restricted stock outstanding and all compensation expense related to these awards had been recognized.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2006 and December 31, 2005 are \$439 and \$234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2005 and December 31, 2004 are \$252 and \$550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are \$1,884 and \$632, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2006 and December 31, 2005 are \$354 and \$1,228, respectively, of accrued interest income. Included in marketable securities at September 30, 2005 and December 31, 2004 are \$1,110 and \$2,607, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as the Company completes activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and

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2006 workforce reductions will approximate \$2.6 million, including \$0.2 million of non-cash expenses in 2005.

Severance costs associated with the workforce reduction plan that were charged to expense, or credited to adjust original cost estimates, during the three and nine months ended September 30, 2006 consist of the following:

	Accrued liability at June 30, 2006	Three months ended September 30, 2006		Accrued liability at September 30, 2006
		Costs charged (credited) to expense	Costs paid or settled in 2006	
Employee severance, payroll taxes, and benefits	\$ 463	\$ (44)	\$ (273)	\$ 146
Other severance costs	1	6	(7)	—
Total	<u>\$ 464</u>	<u>\$ (38)</u>	<u>\$ (280)</u>	<u>\$ 146</u>

	Accrued liability at December 31, 2005	Nine months ended September 30, 2006		Accrued liability at September 30, 2006
		Costs charged to expense	Costs paid or settled in 2006	
Employee severance, payroll taxes, and benefits	\$ 907	\$ 312	\$ (1,073)	\$ 146
Other severance costs	176	26	(202)	—
Total	<u>\$ 1,083</u>	<u>\$ 338</u>	<u>\$ (1,275)</u>	<u>\$ 146</u>

These severance costs are included in the Company's Statement of Operations for the three and nine months ended September 30, 2006 as follows:

Three months ended September 30, 2006	Research & development
Employee severance, payroll taxes, and benefits	\$ (44)
Other severance costs	6
Total	<u>\$ (38)</u>

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Nine months ended September 30, 2006	Research & development	General & administrative
Employee severance, payroll taxes, and benefits	\$ 314	\$ (2)
Other severance costs	26	—
Total	<u>\$ 340</u>	<u>\$ (2)</u>

For segment reporting purposes (see Note 11), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of September 30, 2006 and December 31, 2005 consist of the following:

	September 30, 2006	December 31, 2005
Receivable from the sanofi-aventis Group	\$ 7,326	\$ 36,412
Receivable from Merck & Co., Inc.	511	27
Other	103	82
	<u>\$ 7,940</u>	<u>\$ 36,521</u>

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The Company held no inventories at September 30, 2006. Inventories as of December 31, 2005 consist of the following:

	December 31, 2005
Raw materials	\$ 278
Work-in-process	1,423
Finished products	1,203
	<u>\$ 2,904</u>

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)***8. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses as of September 30, 2006 and December 31, 2005 consist of the following:

	September 30, 2006	December 31, 2005
Accounts payable	\$ 3,657	\$ 4,203
Accrued payroll and related costs	5,952	10,713
Accrued clinical trial expense	2,145	3,081
Accrued expenses, other	2,258	3,048
Interest payable on convertible notes	5,042	2,292
	<u>\$ 19,054</u>	<u>\$ 23,337</u>

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and nine months ended September 30, 2006 and 2005, the components of comprehensive loss are:

	Three months ended September 30,	
	2006	2005
Net loss	\$ (27,410)	\$ (34,652)
Change in net unrealized gain (loss) on marketable securities	378	27
Total comprehensive loss	<u>\$ (27,032)</u>	<u>\$ (34,625)</u>

	Nine months ended September 30,	
	2006	2005
Net loss	\$ (71,366)	\$ (65,774)
Change in net unrealized gain (loss) on marketable securities	375	87
Total comprehensive loss	<u>\$ (70,991)</u>	<u>\$ (65,687)</u>

10. National Institutes of Health Grant

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. The NIH grant provides a minimum of \$17.9 million in funding over a five-year period, subject to compliance with

REGENERON PHARMACEUTICALS, INC.**Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

its terms and annual funding approvals, for the Company's use of its VelociGene® technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells ("ES Cells") which can be used to produce knockout mice. The Company will also receive another \$1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In September 2006, we recognized contract research and development revenue of \$57 from the NIH Grant.

11. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produced an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The table below presents information about reported segments for the three and nine months ended September 30, 2006 and 2005.

	Three months ended September 30, 2006			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 11,448	\$4,176	—	\$ 15,624
Depreciation and amortization	3,447	— ⁽¹⁾	\$ 261	3,708
Non-cash compensation expense	4,632	130	—	4,762
Interest expense	—	—	3,011	3,011
Net (loss) income	(29,379)	1,122	847 ⁽²⁾	(27,410)
Capital expenditures	441	—	—	441

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

	Three months ended September 30, 2005			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 11,533	\$4,661	—	\$ 16,194
Depreciation and amortization	3,674	— ⁽¹⁾	\$ 261	3,935
Non-cash compensation expense	5,703	218	—	5,921
Interest expense	—	—	3,011	3,011
Net (loss) income	(35,802)	1,415	(265) ⁽²⁾	(34,652)
Capital expenditures	575	—	—	575

	Nine months ended September 30, 2006			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 41,026	\$12,075	—	\$ 53,101
Depreciation and amortization	10,413	— ⁽¹⁾	\$ 783	11,196
Non-cash compensation expense	13,220	322	(813) ⁽³⁾	12,729
Interest expense	—	—	9,033	9,033
Net (loss) income	(78,528)	4,359	2,803 ⁽²⁾	(71,366)
Capital expenditures	1,409	—	—	1,409
Total assets	57,530	1,445	296,211 ⁽⁴⁾	355,186

	Nine months ended September 30, 2005			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 38,580	\$10,189	—	\$ 48,769
Depreciation and amortization	10,841	— ⁽¹⁾	\$ 783	11,624
Non-cash compensation expense	17,316	308	—	17,624
Other contract income	30,640	—	—	30,640
Interest expense	—	—	9,035	9,035
Net (loss) income	(67,031)	2,777	(1,520) ⁽²⁾	(65,774)
Capital expenditures	4,327	—	—	4,327
Total assets	72,037	5,380	341,858 ⁽⁴⁾	419,275

(1) Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

- (2) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the nine months ended September 30, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 3).
- (3) Represents the cumulative effect of adopting SFAS 123R (see Note 3).
- (4) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

12. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

13. Future Impact of Recently Issued Accounting Standards

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Management is currently evaluating the potential impact of adopting FIN 48 on the Company's financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. The Company will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 157 on the Company's financial statements.

14. Subsequent Event — New Research and Development Agreement

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC ("Bayer") to globally develop, and commercialize outside the United States, the Company's Vascular Endothelial Growth Factor ("VEGF") Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of \$75.0 million. In addition, the Company is eligible to receive up to \$110.0 million in

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

development and regulatory milestones, including a total of \$40.0 million upon the initiation of Phase 3 trials in defined major indications. The Company is also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

The Company will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, the Company is responsible for any future commercialization of the VEGF Trap-Eye and has retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

2007: Up to \$50.0 million shared equally; we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to the VEGF Trap-Eye.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual 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, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and the IL-1 Trap (rilonacept) in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. In October 2006, we entered into a collaboration with Bayer HealthCare LLC for the development of the VEGF Trap-Eye. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the strength of the VelocImmune platform, which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move two new antibody candidates into clinical trials each year going forward beginning in 2007. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of September 30, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis. Currently, the collaboration is conducting three Phase 2 studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of SMA. In addition, four new Phase 2 single-agent studies are beginning in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas. We and sanofi-aventis are working to finalize plans with NCI/CTEP for at least six additional trials in different cancer types.

Sanofi-aventis and Regeneron intend to conduct three Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, the first of which is planned to begin in early 2007. Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are in progress in a variety of cancer types to support the planned Phase 3 clinical program. The companies have previously summarized information from two of these safety and tolerability trials. One study is evaluating the VEGF Trap in combination with oxaliplatin, 5-fluorouracil, and leucovorin (FOLFOX4) in a Phase 1 trial of patients with advanced solid tumors. Another study is evaluating the VEGF Trap in combination with irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a Phase 1 trial of patients with advanced solid tumors. Abstracts published in the [2006 ASCO Annual Meeting Proceedings](#) reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular

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system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States, of the VEGF Trap-Eye. Under the agreement we and Bayer will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic

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eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare and can earn up to \$110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap outside the United States achieve certain specified levels starting at \$200 million. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Detailed information about this agreement is included in the section below entitled "Collaboration with Bayer HealthCare."

In the second quarter of 2006, we initiated a 150 patient, 12 week, Phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. Regeneron is initiating a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in AMD. A Phase 3 trial of the VEGF Trap-Eye in wet AMD utilizing the new formulation is planned to begin in early 2007.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with DME.

At the 2006 American Society of Retinal Specialists (ASRS) annual meeting in France, we updated the positive preliminary results from a Phase 1 trial of the VEGF Trap-Eye in patients with wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye). Patients were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. In wet AMD, the leakiness of the abnormal blood vessels in the eye can lead to increased retinal thickness. On average, patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness. Excess retinal thickness, as determined by ocular coherence tomography (OCT), is a clinical measure of disease activity in wet AMD. As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness resulting from the disease process was 194 microns at baseline. Following a single intravitreal dose of the VEGF Trap-Eye, median excess retinal thickness was reduced to 60 microns, an improvement that was sustained over a six week period. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline, which was reduced to 27 microns at six weeks after the single dose of the VEGF Trap-Eye.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as £15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at six weeks. In the two highest dose groups (2 mg and 4 mg), the mean

improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis™ (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap (riloncept) — Inflammatory Diseases

The IL-1 Trap (riloncept) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called *CIAS1*-related Autoinflammatory Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In October 2006, we announced positive data from a Phase 3 clinical program designed to provide two separate demonstrations of efficacy for the IL-1 Trap within a single group of adult patients suffering from CAPS. The Phase 3 program of the IL-1 Trap included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: $p < 0.0001$ and Part B: $p < 0.001$). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

We plan to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2007, following completion of a 24-week open-label extension phase. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive the IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ($p < 0.0001$). Following a 9-week interval during which all patients received the IL-1 Trap, a “randomized withdrawal” study (Part B) was performed, in which the same patients were re-randomized to either switch to placebo or continue treatment with the IL-1 Trap in a double-

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blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on the IL-1 Trap who had no significant change ($p < 0.001$). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on the IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. The 24-week open-label extension phase is ongoing.

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin (“icy-fire”). Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of the IL-1 Trap in other indications. In particular, based on preclinical evidence that IL-1 appears to play a critical role in gout, we are preparing to initiate an exploratory study in gout in early 2007. In an ongoing pilot study in systemic juvenile idiopathic arthritis (SJIA), we observed evidence of biological activity and clinical response, but also noted clinical variability across the SJIA patients. While we continue to evaluate the IL-1 Trap in these patients, no new studies are currently planned.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates 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

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addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2006, we had a cumulative loss of \$656.6 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

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 for 2006 and plans over the next 12 months are as follows:

<u>Product Candidate</u>	<u>2006 Events to Date</u>	<u>2006-7 Plans</u>
VEGF Trap — Oncology	<ul style="list-style-type: none">• Initiated Phase 2 studies of the VEGF Trap as a single agent in AOC and NSCLA patients, and in AOC patients with SMA.• Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens• Reported encouraging preliminary results of the safety and tolerability of intravenous VEGF Trap plus FOLFOX4 and of intravenous VEGF Trap plus LV5FU2-CPT11 in separate Phase 1 trials of patients with advanced solid tumors• NCI/CTEP finalized protocols for Phase 2 trials of the VEGF Trap in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas	<ul style="list-style-type: none">• Initiate up to three efficacy/safety studies of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications• Sponsor with the NCI/CTEP at least six additional exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types

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<u>Product Candidate</u>	<u>2006 Events to Date</u>	<u>2006-7 Plans</u>
VEGF Trap-Eye	<ul style="list-style-type: none">• Reported positive preliminary results from Phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg• Initiated Phase 2 trial in wet AMD utilizing intravitreal injections• Initiated safety and tolerability study of the new formulation of the VEGF Trap-Eye in patients with AMD• Initiated Phase 1 trial in DME• Initiated collaboration with Bayer HealthCare	<ul style="list-style-type: none">• Report preliminary results of Phase 2 trial in wet AMD utilizing intravitreal injections• Initiate Phase 3 trial in wet AMD utilizing intravitreal injections of the VEGF Trap-Eye• Explore additional eye disease indications
IL-1 Trap (rilonacept)	<ul style="list-style-type: none">• Reported positive results from efficacy portion of Phase 3 trial of the IL-1 Trap in CAPS• Reported positive preliminary results from ongoing Phase 1 trial in SJIA	<ul style="list-style-type: none">• File Biologics License Application with the FDA for CAPS• Evaluate the IL-1 Trap in other disease indications in which IL-1 may play an important role

Collaboration with Bayer Healthcare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the VEGF Trap-Eye. Under the terms of the agreement, Bayer made a non-refundable up-front payment to us of \$75.0 million. In addition, we are eligible to receive up to \$110.0 million in development and regulatory milestones, including a total of \$40.0 million upon the initiation of Phase 3 trials in defined major indications such as wet AMD and DME. We are also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

We will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, we are responsible for any future commercialization of the VEGF Trap-Eye and have retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

2007: Up to \$50.0 million shared equally; we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

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If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We will use our VelociGene® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We have also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our VelociGene technology in the Knockout Mouse Project. We will generate a collection of targeting vectors and targeted mouse embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we will be entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We will have the right to use, for any purpose, all materials generated by us and the research consortium.

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation- Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions

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in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to our cash flows for these respective periods.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards (“Stock Option Expense”) recognized in operating expenses totaled \$4.8 million and \$5.4 million, respectively, which, in both periods, included \$0.1 million in each period of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled \$13.2 million and \$16.2 million, respectively. In addition, for the nine months ended September 30, 2005, \$0.1 million of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was \$19.1 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options’ performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options’ expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options’ expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average

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values of the assumptions we used in computing the fair value of option grants during the three and nine months ended September 30, 2006 and 2005:

	<u>Three months ended September 30,</u>	
	<u>2006</u>	<u>2005</u>
Expected volatility	65%	70%
Expected lives from grant date	5.5 years	5.0 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.74%	4.00%

	<u>Nine months ended September 30,</u>	
	<u>2006</u>	<u>2005</u>
Expected volatility	67%	75%
Expected lives from grant date	6.5 years	6.2 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.76%	3.96%

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended September 30, 2006 and 2005

Net Loss:

We reported a net loss of \$27.4 million, or \$0.48 per share (basic and diluted), for the third quarter of 2006 compared to a net loss of \$34.7 million, or \$0.62 per share (basic and diluted), for the third quarter of 2005.

Revenues:

Revenues for the three months ended September 30, 2006 and 2005 consist of the following:

<i>(In millions)</i>	<u>2006</u>	<u>2005</u>	<u>Increase (Decrease)</u>
Contract research & development revenue			
The sanofi-aventis Group	\$ 10.0	\$ 11.2	\$ (1.2)
Other	1.4	0.3	1.1
Total contract research & development revenue	11.4	11.5	(0.1)
Contract manufacturing revenue	4.2	4.7	(0.5)
Total revenue	<u>\$ 15.6</u>	<u>\$ 16.2</u>	<u>\$ (0.6)</u>

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and

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2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

<i>(In millions)</i>	Three months ended September 30,	
	2006	2005
Regeneron expense reimbursement	\$ 7.0	\$ 8.9
Recognition of deferred revenue related to up-front payments	3.0	2.3
Total	<u>\$ 10.0</u>	<u>\$ 11.2</u>

Sanofi-aventis' reimbursement of our VEGF Trap expenses decreased in the third quarter of 2006 from the same period in 2005, primarily due to lower costs in the third quarter of 2006 related to our manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments increased in the third quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of September 30, 2006, \$72.2 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract manufacturing revenue relates to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue decreased in the third quarter of 2006 from the same period of 2005 as we shipped less product to Merck in 2006. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the third quarter of 2006 and 2005 were \$0.4 million and \$0.5 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. Merck deferred revenue has been recognized as product is shipped, based upon Merck's order quantities during the term of the agreement. In September 2006, we made the final shipment of product to Merck under the Merck agreement and the remaining deferred revenue associated with the capital improvement reimbursements was recognized. Subsequent to the October 2006 expiration of the Merck agreement, we do not expect to receive any further contract manufacturing revenue from Merck.

Expenses:

Total operating expenses decreased to \$43.9 million in the third quarter of 2006 from \$50.6 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 574 in the third quarter of 2006 from 728 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

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Operating expenses in the third quarter of 2006 and 2005 include a total of \$4.7 million and \$5.5 million of Stock Option Expense, respectively, as detailed below:

<i>(In millions)</i>	For the three months ended September 30, 2006		
	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	\$ 32.1	\$ 2.7	\$ 34.8
Contract manufacturing	3.0	0.1	3.1
General and administrative	4.1	1.9	6.0
Total operating expenses	<u>\$ 39.2</u>	<u>\$ 4.7</u>	<u>\$ 43.9</u>

<i>(In millions)</i>	For the three months ended September 30, 2005		
	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	\$ 37.8	\$ 3.3	\$ 41.1
Contract manufacturing	3.0	0.3	3.3
General and administrative	4.3	1.9	6.2
Total operating expenses	<u>\$ 45.1</u>	<u>\$ 5.5</u>	<u>\$ 50.6</u>

Research and Development Expenses:

Research and development expenses decreased to \$34.8 million in the third quarter of 2006 from \$41.1 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2006 and 2005:

<i>(In millions)</i>	Three months ended September 30,		
	2006	2005(1)	Increase (Decrease)
Research and development expenses			
Payroll and benefits (2)	\$ 11.0	\$ 12.8	(\$1.8)
Clinical trial expenses	3.1	7.5	(4.4)
Clinical manufacturing costs (3)	10.0	10.8	(0.8)
Research and preclinical development costs	5.5	4.5	1.0
Occupancy and other operating costs	5.2	5.5	(0.3)
Total research and development	<u>\$ 34.8</u>	<u>\$ 41.1</u>	<u>(\$6.3)</u>

- (1) For the major categories of research and development expenses, amounts for the three months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the three months ended September 30, 2005 are unchanged from amounts previously reported.
- (2) Includes \$2.3 million and \$2.8 million of Stock Option Expense for the three months ended September 30, 2006 and 2005, respectively.
- (3) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.5 million of Stock Option Expense for both the three months ended September 30, 2006 and 2005.

Payroll and benefits decreased principally due to our lower headcount in the third quarter of 2006, as described above. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006, as we discontinued clinical development of the IL-1 Trap in adult rheumatoid

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arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased as we were not actively manufacturing clinical supplies of our drug candidates during the third quarter of 2006. Research and preclinical development costs increased primarily due to higher third-party pre-clinical testing costs in connection with our VEGF Trap and VEGF Trap-Eye programs. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to \$3.1 million in the third quarter of 2006 from \$3.3 million in the comparable quarter of 2005 primarily because we shipped less product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to \$6.0 million in the third quarter of 2006 from \$6.2 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and legal expenses related to general corporate matters.

Other Income and Expense:

Investment income increased to \$3.9 million in the third quarter of 2006 from \$2.7 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$3.0 million in the third quarter of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Nine Months Ended September 30, 2006 and 2005

Net Loss:

We reported a net loss of \$71.4 million, or \$1.25 per share (basic and diluted), for the first nine months of 2006 compared to a net loss of \$65.8 million, or \$1.18 per share (basic and diluted), for the same period of 2005. Results for the first nine months of 2005 included a \$25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap-Eye.

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Revenues:

Revenues for the nine months ended September 30, 2006 and 2005 consist of the following:

<i>(In millions)</i>	<u>2006</u>	<u>2005</u>	<u>Increase (Decrease)</u>
Contract research & development revenue			
The sanofi-aventis Group	\$ 38.7	\$ 30.4	\$ 8.3
The Procter & Gamble Company	—	6.0	(6.0)
Other	2.3	2.2	0.1
Total contract research & development revenue	41.0	38.6	2.4
Contract manufacturing revenue	12.1	10.2	1.9
Total revenue	<u>\$ 53.1</u>	<u>\$ 48.8</u>	<u>\$ 4.3</u>

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104.

Sanofi-aventis Contract Research & Development Revenue

<i>(In millions)</i>	<u>Nine months ended September 30,</u>	
	<u>2006</u>	<u>2005</u>
Regeneron expense reimbursement	\$ 29.6	\$ 23.4
Recognition of deferred revenue related to up-front payments	9.1	7.0
Total	<u>\$ 38.7</u>	<u>\$ 30.4</u>

Sanofi-aventis' reimbursement of our VEGF Trap expenses increased in the first nine months of 2006 from the same period in 2005, primarily due to higher costs related to our manufacture of VEGF Trap clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first nine months of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

Contract research and development revenue earned from Procter & Gamble decreased in the first nine months of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

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Contract manufacturing revenue increased in the first nine months of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Included in contract manufacturing revenue in the first nine months of 2006 and 2005 were \$1.2 million and \$1.1 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production.

Expenses:

Total operating expenses decreased to \$127.3 million in the first nine months of 2006 from \$143.7 million in the same period of 2005, due, in part, to our lower headcount, as previously described above. (Also see "Severance Costs" below.)

Operating expenses in the first nine months of 2006 and 2005 include a total of \$13.2 million and \$16.2 million of Stock Option Expense, respectively, as detailed below:

<i>(In millions)</i>	<u>For the nine months ended September 30, 2006</u>		
	<u>Expenses before inclusion of Stock Option Expense</u>	<u>Stock Option Expense</u>	<u>Expenses as Reported</u>
<u>Expenses</u>			
Research and development	\$ 94.0	\$ 7.3	\$ 101.3
Contract manufacturing	7.4	0.3	7.7
General and administrative	12.7	5.6	18.3
Total operating expenses	<u>\$ 114.1</u>	<u>\$ 13.2</u>	<u>\$ 127.3</u>

<i>(In millions)</i>	<u>For the nine months ended September 30, 2005</u>		
	<u>Expenses before inclusion of Stock Option Expense</u>	<u>Stock Option Expense</u>	<u>Expenses as Reported</u>
<u>Expenses</u>			
Research and development	\$ 107.6	\$ 10.1	\$ 117.7
Contract manufacturing	7.1	0.3	7.4
General and administrative	12.8	5.8	18.6
Total operating expenses	<u>\$ 127.5</u>	<u>\$ 16.2</u>	<u>\$ 143.7</u>

Research and Development Expenses:

Research and development expenses decreased to \$101.3 million in the first nine months of 2006 from \$117.7 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2006 and 2005:

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(In millions)

	Nine months ended September 30,		
	2006	2005(1)	Increase (Decrease)
Research and development expenses			
Payroll and benefits (2)	\$ 32.7	\$ 38.4	\$ (5.7)
Clinical trial expenses	11.0	16.1	(5.1)
Clinical manufacturing costs (3)	28.3	32.1	(3.8)
Research and preclinical development costs	13.3	14.5	(1.2)
Occupancy and other operating costs	16.0	16.6	(0.6)
Total research and development	<u>\$ 101.3</u>	<u>\$ 117.7</u>	<u>\$ (16.4)</u>

- (1) For the major categories of research and development expenses, amounts for the nine months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the nine months ended September 30, 2005 are unchanged from amounts previously reported.
- (2) Includes \$6.1 million and \$8.4 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.
- (3) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.2 million and \$1.6 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first nine months of 2006. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006 as we discontinued clinical development of the IL-1 Trap in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing IL-1 Trap clinical supplies, which were partially offset by higher costs related to manufacturing VEGF Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to \$7.7 million in the first nine months of 2006 from \$7.4 million in the comparable period of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to \$18.3 million in the first nine months of 2006 from \$18.6 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and administrative personnel-related costs.

Other Income and Expense:

As described above, in January 2005 we received a one-time \$25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first nine months of 2005.

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In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time \$5.6 million payment to us, which we recognized as other contract income in the first nine months of 2005.

Investment income increased to \$11.0 million in the first nine months of 2006 from \$7.5 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$9.0 million in the first nine months of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis and Merck, and investment income.

Nine Months Ended September 30, 2006 and 2005

Cash Used in Operations:

At September 30, 2006, we had \$289.6 million in cash, cash equivalents, and marketable securities compared with \$316.7 million at December 31, 2005. In January 2006, we received a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first nine months of 2006, our net loss was \$71.4 million; however, cash used in our operations was only \$30.2 million, principally because (i) the above-described \$25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006, and (ii) we recognized non-cash compensation expense of \$13.5 million and depreciation and amortization of \$11.2 million for the first nine months of 2006. In the first nine months of 2005, our net loss was \$65.8 million; however, cash used in our operations was only \$10.4 million, principally due to (i) receipts during this period from the sanofi-aventis Group for reimbursement of VEGF Trap development expenses incurred by us and a \$25.0 million clinical milestone payment earned in December 2004 and (ii) recognition of non-cash compensation expense of \$17.6 million and depreciation and amortization of \$11.6 million for the first nine months of 2005.

Cash (Used in) Provided by Investing Activities:

Net cash provided by investing activities was \$8.1 million in the first nine months of 2006 compared to \$90.2 million in the same period of 2005, due primarily to a decrease in sales or maturities of marketable securities net of purchases. In the first nine months of 2006, sales or maturities of marketable securities exceeded purchases by \$9.7 million, whereas in the same period of 2005, sales or maturities of marketable securities exceeded purchases by \$94.8 million.

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Cash Provided by Financing Activities:

Cash provided by financing activities increased to \$5.3 million in the first nine months of 2006 from \$1.1 million in the same period in 2005 due primarily to an increase in payments in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

The Bayer Healthcare Agreement:

Under our collaboration agreement with Bayer, Bayer made a non-refundable, up-front payment of \$75.0 million to us in October 2006. Agreed upon development expenses incurred by both companies during the term of the collaboration will be shared as follows:

2007: Up to \$50.0 million shared equally; we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

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Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as we complete activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and 2006 workforce reductions will approximate \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.4 million was charged to expense in the first nine months of 2006.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$1.8 million and \$4.3 million for the first nine months of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately \$2 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer. We have entered into discussions regarding a new long-term operating lease for our laboratory and office facilities in Tarrytown, New York, as the operating lease for our current Tarrytown facilities expires in December of 2007 and 2009. We expect to continue to

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incur significant lease costs in future years. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of September 30, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to \$200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the nine months ended September 30, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Future Impact of Recently Issued Accounting Standards

In July 2006, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. 48 (“FIN 48”), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Our management is currently evaluating the potential impact of adopting FIN 48 on our financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (“GAAP”), and expands disclosures about fair value measurements. We will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 157 on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately \$0.5 million and \$0.8 million change in the fair market value of our investment portfolio at September 30, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at September 30, 2006, compared to September 30, 2005, is due to decreases in our investment portfolio’s balance and duration to maturity at the end of September 2006 versus the end of September 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief 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 (the “Exchange Act”), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief 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 within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

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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 September 30, 2006 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

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

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, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2006, we had a cumulative loss of \$656.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Until October 31, 2006, we received contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck expired in October 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will 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.

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We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may 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 contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate 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 will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. 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. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

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We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials 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, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include 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. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the phase 3 clinical program for the IL-1 Trap in CAPS (CIAS1-related Autoinflammatory Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of the IL-1 Trap.

The efficacy and safety data from the phase 3 clinical program for the IL-1 Trap in CAPS may be inadequate to support approval for its commercialization in this indication. Moreover, if the safety data from the ongoing clinical trials testing the IL-1 Trap are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for the IL-1 Trap or we may be forced to delay the filing. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance. Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for the IL-1 Trap, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize the IL-1 Trap profitably.

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, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the IL-1 Trap in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

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. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller 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 has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel[®] (Amgen) and Remicade[®] (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of the IL-1 Trap.

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 appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created

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at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents 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 exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. 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 may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have

blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. 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. 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 product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

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If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

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 sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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

As a biopharmaceutical company with significant 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, viruses, 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.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an

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unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We will rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration

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agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

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

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. 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 or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers 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. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

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We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce API for our own clinical and preclinical candidates. Under a long-term manufacturing agreement with Merck, which expired in October 2006, we also produced an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. Since we no longer use our facilities to manufacture the Merck intermediate, and if clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical 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 are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and 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 large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings.

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This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor (Macugen®) for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis™) for the treatment of wet AMD and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The National Eye Institute has recently received funding for a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. The marketing approval of Macugen and Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis or Macugen, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

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We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS1* gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our 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, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We intend to file an application with the FDA seeking approval to market the IL-1 Trap for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize the IL-1 Trap. Physicians may not prescribe the IL-1 Trap and CAPS patients may not be able to afford the IL-1 Trap if third party payers do not agree to reimburse the cost of IL-1 Trap therapy and this would adversely affect our ability to commercialize the IL-1 Trap profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including the IL-1 Trap, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union 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 are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

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 our executive officers. If we are not able to retain any of these persons or our Chairman, 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 Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Therapeutics and Clinical Program Development, Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations, and Peter Powchik, M.D., our Senior Vice President, Clinical Development. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

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:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

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. Broad market fluctuations may also adversely affect the market price of our common stock.

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 September 30, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 46.6% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. As of September 30, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, 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.

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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 September 30, 2006, holders of Class A Stock held 29.5% of the combined voting power of all 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 to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of September 30, 2006:

- our current officers and directors beneficially owned 14.4% 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 September 30, 2006, and 33.1% 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 September 30, 2006; and
- our seven largest shareholders beneficially owned 46.6% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. In addition, these seven shareholders held 53.4% 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 and our Chairman which are exercisable within 60 days of September 30, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other “change in control” of us and could adversely affect the price of our common stock.

Our amended and restated 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 you and other 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 shareholders;
- a staggered board of directors, so that it would take three successive annual 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

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for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;

- 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;
- 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, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *“Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.”*

In addition, we have a Change in Control Severance Plan and many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a “change in control” of the Company, as defined in the plan.

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Item 6. Exhibits

(a) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
10.1	— License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
12.1	— Statement re: computation of ratio of earnings to combined fixed charges.
31.1	— Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	— Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

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: November 6, 2006

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration, Chief
Financial Officer, Treasurer, and
Assistant Secretary

LICENSE AND COLLABORATION AGREEMENT

By and Between

BAYER HEALTHCARE LLC

and

REGENERON PHARMACEUTICALS, INC.

Dated as of October 18, 2006

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LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (“Agreement”), dated as of October 18, 2006 (the “Effective Date”), is by and between BAYER HEALTHCARE LLC, a Delaware limited liability company having a principal place of business at 511 Benedict Avenue, Tarrytown, New York 10591 (“Company”), and REGENERON PHARMACEUTICALS, INC., a New York corporation having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 (“Regeneron”) (with each of Company and Regeneron referred to herein individually as a “Party” and collectively as the “Parties”).

WHEREAS, Regeneron owns and has licensed certain Patents, Know-How and other rights related to the VEGF Trap in the Territory;

WHEREAS, Company and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory; and

WHEREAS, Regeneron and Company desire to collaborate on the Development and Manufacture of Products in the Field, and the Commercialization of Products in the Field in the Territory under the terms and conditions set forth herein (the “Collaboration”).

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 “Affiliate” shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such 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: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. 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 and policies of such entity.

1.2 “Agreement” shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.3 “Anticipated First Commercial Sale” shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.

1.4 “Approval” shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.5 “Aventis” shall mean sanofi-aventis US LLC (successor in interest to Aventis Pharmaceuticals, Inc.

1.6 “Aventis Agreement” shall mean the Collaboration Agreement, dated as of September 3, 2003, by and between Aventis and Regeneron Pharmaceuticals, Inc., as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, and the Fourth Amendment, dated as of January 31, 2006, as the same may be further amended from time to time.

1.7 “Business Day” shall mean a day on which commercial banking institutions in New York, New York are open for business.

1.8 “Change of Control” shall mean, with respect to Regeneron, any of the following events: (a) any Person is or 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, 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 a majority of the total voting power represented by all classes of capital stock then outstanding of Regeneron normally entitled to vote in elections of directors; (b) Regeneron consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into Regeneron, other than (i) a merger or consolidation which would result in the voting securities of Regeneron 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 Regeneron or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (ii) a

merger or consolidation effected to implement a recapitalization of Regeneron (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of Regeneron representing a majority of the combined voting power of Regeneron's then outstanding securities; or (c) Regeneron conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly-owned Affiliate of Regeneron.

1.9 "Class A Stock" shall mean the Class A Stock of Regeneron, par value \$0.001 per share.

1.10 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the Development Plans, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the Development Plans, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging and labeling such Clinical Supply Requirements, comparator agent and/or placebo, as the case may be, for activities contemplated under the Development Plans and (d) any VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements.

1.11 "Clinical Supply Requirements" shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.

1.12 "COGS" for a Quarter shall mean cost (calculated in accordance with GAAP or IAS/IFRS) of Manufacturing the Licensed Products sold in the Field in the Territory in the Quarter.

1.13 "Commercialize" or "Commercialization" shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, offering for sale, having sold and/or selling a Licensed Product in the Field in the Territory, including, without limitation, market research, pre-launch marketing and educational activities, sampling and Non-Approval Trials in the Territory.

1.14 "Commercial Overhead Charge" shall mean, on a country-by-country basis in the Territory, beginning in the Contract Year of First Commercial Sale in the applicable country, an amount (agreed upon by the JFC at least eighteen (18) months prior to the Anticipated First Commercial Sale in the country) to cover [*****], such amount to be determined by the JFC as of January 1 of each following Contract Year. For the avoidance of doubt, "Commercial Overhead Charge" shall not include any amounts included in Medical Affairs Cost, Sales Force Cost, Other Shared Expenses or Shared Promotion Expenses.

1.15 “Commercially Reasonable Efforts” shall mean, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be consistent with the Collaboration Purpose and substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it, which product is at a similar stage in its development or product life and is of similar market potential (taking into consideration both anticipated total sales and overall profitability). Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the Territory Profit Split nor other payments made or required to be made from one Party to the other under this Agreement shall be considered in determining market potential (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must pay the Territory Profit Split or make milestone or any other payments hereunder to the other Party). By way of example, for purposes of determining whether Company uses Commercially Reasonable Efforts to Commercialize a Licensed Product in a Major Market Country, a basis for comparison shall be the efforts used by Company to commercialize in such Major Market Country another Company product that is wholly owned by Company, is at a similar stage of commercialization to the Licensed Product and has both anticipated total sales and overall profitability to Company in such Major Market Country substantially similar to that of the Licensed Product, taking into account total sales and total profitability of the Licensed Product in such Major Market Country, but without consideration of any of the payments required to be made from one Party to the other under this Agreement.

1.16 “Commercial Supply Cost” shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of the Commercial Supply Requirements, including, without limitation, any filling, packaging and labeling costs, and any VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.17 “Commercial Supply Requirements” shall mean, with respect to each Licensed Product, quantities of Finished Product as are required by Company to fulfill its (or its Affiliate’s or Sublicensee’s) requirements for commercial sales, Non-Approval Trials and Product sampling with respect to such Licensed Product in the Field in the Territory.

1.18 “Committee” means any of the JSC, JDC, JCC or JFC, each as described in Article 3 (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).

1.19 "Common Stock" shall mean the common stock of Regeneron, par value \$0.001 per share.

1.20 "Company Excluded Territory Intellectual Property" shall mean Company Patent Rights and Know-How that cover, claim or are used for the Development, Manufacture and/or Commercialization of Regeneron Products under the Plans, but excluding (a) any Company Patent Rights covering the composition of any Company Products, and (b) any New Information or Party Information arising from the Development, Manufacture and/or Commercialization of Company Products.

1.21 "Company Intellectual Property" shall mean the Company Patent Rights and any Know-How of Company or any of its Affiliates.

1.22 "Company Patent Rights" shall mean those Patent Rights which (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Company or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, Patent Rights covering any formulation and delivery technologies, with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Product in the Field.

1.23 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Company (based on information reported under Sections 5.4 and 9.3) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Promotion Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter under the Global Development Plan and the Territory Development Plan, (c) Other Shared Expenses incurred by each Party for such Quarter, including the allocation of global costs pursuant to Section 3.4(b)(xii), (d) Commercial Supply Costs incurred by each Party for such Quarter and (e) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.

1.24 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2007, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.

1.25 "Controlling Party" shall mean Regeneron with respect to the filing, prosecution and maintenance of a Joint Patent Right that claims or covers a Regeneron Product (or the Manufacture or use thereof), and Company in the case of all other Joint Patent Rights.

1.26 "Country Commercialization Budget" shall mean the three-year rolling budget(s) approved by the JCC for a particular Country Commercialization Plan.

1.27 “Country Commercialization Plan” shall mean, for each Major Market Country in the Territory, the three-year rolling plan for Commercializing Licensed Products in the Field in such country, including the applicable Country Commercialization Budget, developed and approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.

1.28 “Country Commercialization Report” shall mean, for each Major Market Country in the Territory, a written report summarizing the marketing, detailing, selling and promotional activities undertaken by Company (or its Affiliate) during the previous Quarter in connection with the applicable Country Commercialization Plan, including the number of details for the Licensed Product in the Field in the country, together with a detailed project-level statement of Shared Promotion Expenses (calculated in U.S. dollars and local currency) incurred by Company (or its Affiliate) during such Quarter in the country.

1.29 “CPI” for the Excluded Territory shall mean the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index). For countries and Regions in the Territory (other than Japan), “CPI” shall mean the “EU15 CPI” (or its successor equivalent index), which is published monthly and available via Bloomberg Professional, as published by Bloomberg L.P. In Japan, “CPI” shall mean such other inflation measure or rate agreed upon by the Parties.

1.30 “Develop” or “Development” shall mean (a) activities directly and specifically relating to research, pre-clinical and clinical drug development of a Licensed Product in the Field, including, without limitation, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation, submission and maintenance of Registration Filings and Approvals (including post-marketing clinical trials imposed by applicable Law or as required by a Regulatory Authority) and activities necessary to obtain a Pricing Approval, reimbursement and/or listing on health care providers’ and payers’ formularies, and (b) any other development activities with respect to a Licensed Product in the Field, including, without limitation, activities to support new product formulations, delivery technologies and/or new indications in the Field either before or after the First Commercial Sale.

1.31 “Development Costs” shall mean costs incurred by a Party in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the Development Plan(s) (or prior to the first Development Plan, the Initial Development Plan), including without limitation:

(a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining and maintaining Registration Filings and Approvals (including Pricing Approvals) necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;

(b) Development FTE Costs;

(c) Clinical Supply Costs;

(d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation, (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);

(e) Pre-Launch Marketing Expenses;

(f) any license fees and other payments under Existing Licenses and New Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory (which, for the avoidance of doubt, include activities in the Excluded Territory performed under the Global Development Plan); and

(g) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.

For clarity, it is the intent of the Parties that costs included in the foregoing will not be unfairly allocated to the Licensed Products in the Field (to the extent that any development cost is attributable, in part, to products or activities outside the scope of this Agreement). For the avoidance of doubt, [*****] and as defined therein shall be considered a Development Cost under the Global Development Plan under this Agreement

1.32 "Development FTE Cost" shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the

product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate.

1.33 "Development FTE Rate" for the Excluded Territory, the Territory (other than Japan) and Japan shall mean [*****] in the first Contract Year, such amount to be adjusted as of January 1, 2008 and annually thereafter by the percentage increase or decrease, if any, in the applicable CPI (determined based on the location of the Development personnel) since the Effective Date or the latest adjustment date hereunder, whichever is later, through June 30 of the prior calendar year. The Development FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.34 "Development Plan(s)" shall mean the Global Development Plan and the Territory Development Plan.

1.35 "Effective Date" shall have the meaning set forth in the introductory paragraph.

1.36 "EMA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

1.37 "Excluded Territory" shall mean the United States.

1.38 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Bayer HealthCare AG, a German corporation having a principal place of business at 51368 Leverkusen, Germany.

1.39 "Existing Licenses" shall mean the agreements listed in Schedule 4.

1.40 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.41 "Field" shall mean the treatment and/or diagnosis of any ocular disease or disorder through the local administration of any product to the eye, including, without limitation, by topical, intravitreal, periorbital, implants or other means of local administration to the eye.

1.42 "Finished Product" shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.

1.43 "First Commercial Sale" shall mean, with respect to a Licensed Product in a country in the Territory (or, solely for purposes of Section 19.7(c), in the Excluded Territory), the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

1.44 “Formulated Bulk Product” shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.45 “FTE” shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified 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 [*****] per year.

1.46 “GAAP” shall mean generally accepted accounting principles in the United States.

1.47 “Global Development Budget” shall mean the three-year rolling budget(s) approved by the JSC in the Global Development Plan.

1.48 “Global Development Plan” shall mean the three-year rolling plan approved by the JSC for Developing Licensed Products in the Field as part of an integrated worldwide Development program, including the related Global Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Global Development Plan activities may be undertaken entirely or partially in the Excluded Territory if approved by the JSC. For the avoidance of doubt, the Global Development Plan will not include (a) any Development activities that are conducted or sponsored by a Party which are only required for a specific Approval in the Territory (including activities under the Territory Development Plan) or the Excluded Territory, (b) Non-Approval Trials or (c) any studies conducted for Pricing Approval or formulary approval.

1.49 “Good Practices” shall mean compliance with the applicable standards contained in then-current “Good Laboratory Practices,” “Good Manufacturing Practices” and/or “Good Clinical Practices,” as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.

1.50 “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 any supranational organization of which any such country is a member.

1.51 “IAS/IFRS” shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.52 “ICH” shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.53 “IND” shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Product, as

described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.

1.54 “Joint Patent Rights” shall mean Patent Rights that cover a Joint Invention.

1.55 “Know-How” shall mean any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) which (a) are now or hereafter during the Term owned by, licensed to or otherwise held by (i) a Party, (ii) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement or (iii) any of Regeneron’s Affiliates, with the rights to license or sublicense the same, and (b) relate to a Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Product in the Field, including, without limitation, New Information.

1.56 “Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

1.57 “Lead Regulatory Party” shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.

1.58 “Legal Dispute” shall mean any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement.

1.59 “Licensed Products” shall mean Regeneron Products and Company Products.

1.60 “Major Market Country” shall mean [*****] and [*****].

1.61 “Manufacture” or “Manufacturing” shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.

1.62 “Marketing Approval” shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.

1.63 “Medical Affairs Cost” shall mean, for each country in the Territory, the product of (a) the number of office-based FTEs supporting the coordination of Non-Approval Trials related to the Licensed Products in the Field as agreed upon in the

Country Commercialization Plan or Territory Commercialization Plan and (b) the applicable Medical Affairs FTE Rate.

1.64 “Medical Affairs FTE Rate” shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Affairs FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.65 “Net Sales” shall mean the gross amount invoiced for bona fide arms’ length sales of Licensed Products in the Field in the Territory by or on behalf of Company or its Affiliates or Sublicensees to Third Parties, less the following deductions determined in accordance with Company’s standard methods as generally and consistently applied by Company:

- (a) normal and customary trade, cash and/or quantity discounts allowed and taken with respect to Licensed Product sales;
- (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates and allowances;
- (c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;
- (d) Third Party cash rebates and chargebacks related to sales of the Licensed Product, to the extent allowed;
- (e) retroactive price reductions that are actually allowed or granted;
- (f) compulsory payments and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;
- (g) freight, insurance and other transportation charges, to the extent included in the invoice price;
- (h) tariffs, duties, excise, value-added, consumption or other taxes (other than taxes based on income), to the extent included in the invoice price; and

(i) any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within categories substantially equivalent to those listed above.

Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Company or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), Net Sales of such Combination Product for the purpose of determining the Territory Profit Split pursuant to this Agreement will be calculated by multiplying actual Net Sales of such Combination Product as determined in the first paragraph of this definition of "Net Sales" by the fraction $A/(A+B)$, where A is the invoice price of such Licensed Product if sold separately, and B is the total invoice price of the other active ingredient(s) in the combination if sold separately. If, on a country-by-country basis, such other active ingredient(s) in the Combination Product is not sold separately in such country, but the Licensed Product component of the Combination Product is sold separately in such country, Net Sales for the purpose of determining Territory Profit Split pursuant to this Agreement for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction A/C , where A is the invoice price of the Licensed Product component if sold separately, and C is the invoice price of the Combination Product. If, on a country-by-country basis, the Licensed Product component is not sold separately in that country, Net Sales for the purpose of determining the Territory Profit Split pursuant to this Agreement for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction $D/(D+E)$, where D is the fair market value of the portion of the Combination Product that contains the Licensed Product and E is the fair market value of the portion of the Combination Product containing the other active ingredient(s) included in such Combination Product, as such fair market values are determined by mutual agreement of the Parties through the JFC.

1.66 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by (a) either Party, (b) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement, (c) any of Regeneron's Affiliates or (d) the Parties or their Affiliates jointly, during the Term pursuant to this Agreement to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.

1.67 “New License” shall mean any license approved by the JSC, other than Existing Licenses, required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.68 “Other Shared Expenses” shall mean those costs and expenses specifically referred to in Sections 3.4(b)(xii), 7.7, 12.2(e), 12.3(b), 13.1(c), 13.3(b), 13.3(d) and 17.1(c) which, except as set forth in Section 3.4(b)(xii) or elsewhere in this Agreement, shall be shared equally between the Parties.

1.69 “Out-of-Pocket Costs” shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with the applicable Plan.

1.70 “Party Information” shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party’s or its Affiliates’ technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party’s Affiliates to the other Party or the other Party’s Affiliates in connection with this Agreement. For the avoidance of doubt, all confidential information disclosed by Regeneron under the terms of the confidentiality agreement between the Parties dated July 6, 2006 is hereby deemed Party Information of Regeneron.

1.71 “Patent Application” shall mean any application for a Patent.

1.72 “Patent Rights” shall mean unexpired Patents and Patent Applications.

1.73 “Patents” shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.

1.74 “Person” shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

1.75 “Phase 2 Trial” shall mean a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.

1.76 “Phase 3 Trial” shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one Phase 2 Trial.

1.77 “Plan” shall mean any Country Commercialization Plan, Territory Commercialization Plan, Global Development Plan, Territory Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of Licensed Products in the Field under this Agreement.

1.78 “Pre-Launch Marketing Expenses” shall mean, on a country-by-country basis in the Territory, with respect to each Licensed Product, all Commercialization expenses to support the Licensed Products in the Field incurred prior to the First Commercial Sale of such Licensed Product in the Field in the country.

1.79 “Pricing Approval” shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.80 “Product” shall mean [*****]. Except as expressly set forth herein, the defined term “Product” shall refer exclusively to any such molecule Manufactured, Developed and/or Commercialized in the Field.

1.81 “Product Trademark” shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.

1.82 “Promotional Materials” shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.83 “Quarter” or “Quarterly” shall refer to a calendar quarter, except that the first Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.

1.84 “Regeneron Excluded Territory Intellectual Property” shall mean Regeneron Patent Rights and Know-How that cover, claim or are used for the Development, Manufacture and/or Commercialization of Company Products under the Plans, but excluding (a) any Regeneron Patent Rights covering the composition of any Regeneron Products, including, without limitation, the VEGF Trap, and (b) any New

Information or Party Information arising from the Development, Manufacture and/or Commercialization of Regeneron Products.

1.85 “Regeneron Intellectual Property” shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

1.86 “Regeneron Patent Rights” shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, Patent Rights covering formulation and delivery technologies, with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Product in the Field.

1.87 “Regeneron Products” shall mean Products which are now or hereafter during the Term owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, the VEGF Trap.

1.88 “Region” shall mean [*****] and [*****].

1.89 “Registration Filing” shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.

1.90 “Regulatory Authority” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term “Regulatory Authority” includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.

1.91 “Rest of World Country” shall mean any country in the Territory other than the Major Market Countries.

1.92 “Sales Force Cost” shall mean, for a country in the Territory, the product of (a) the number of FTEs detailing the Licensed Products in the Field in the country in accordance with the approved Country Commercialization Plan and (b) the applicable Sales Force FTE Rate. Notwithstanding the foregoing, neither “Sales Force Cost” nor, for clarity, “Shared Promotion Expenses,” shall include the costs related to [*****]

1.93 “Sales Force FTE Rate” shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of

pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.94 “Shared Promotion Expenses” shall mean the sum of the following items, in each case to the extent attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country Commercialization Plan or Territory Commercialization Plan:

- (a) [*****] to cover the cost of distribution, freight, insurance and warehousing, related to the sale of Licensed Products in the Field in the Territory;
- (b) bad debt attributable to Licensed Products in the Field sold in the Territory;
- (c) Sales Force Cost;
- (d) Medical Affairs Cost;
- (e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;
- (f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion (i) relate to both Licensed Products and other Company products or (ii) relate to Licensed Products in the Field in both the Territory and the Excluded Territory, in each case, as agreed upon in an approved Territory Commercialization Plan or Country Commercialization Plan;
- (g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, 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 included in Commercial Supply Cost; and

(h) Commercial Overhead Charge.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will not be unfairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Promotion Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

1.95 “Shares of Then Outstanding Capital Stock” shall mean, at any time, the issued and outstanding shares of Common Stock and Class A Stock of Regeneron at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend or reclassification of Common Stock or Class A Stock distributable, on a pro rata basis, to all holders of Common Stock and Class A Stock.

1.96 “Sublicensee” shall mean a Third Party or an Affiliate to whom Company will have granted a license or sublicense under Company’s rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a “Sublicensee” will include a Third Party to whom Company will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Company a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.

1.97 “Territory Commercialization Budget” shall mean the three-year rolling budget(s) included in the Territory Commercialization Plan.

1.98 “Territory Commercialization Plan” shall mean the three-year rolling plan for Commercializing the Licensed Products in the Field in the Territory approved by the JSC, including the Territory Commercialization Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. The Territory Commercialization Plan shall set forth for each Licensed Product, the information, plans and forecasts set forth in Section 6.2.

1.99 “Territory” shall mean all the countries of the world, except the Excluded Territory.

1.100 “Territory Development Plan” shall mean the three-year rolling plan approved by the JSC for Developing the Licensed Products in the Field for a specific country (or countries) in the Territory, including the related Territory Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, the Territory Development Plan will not include (a) any Development activities that are conducted as part of the Global Development Plan or (b) Non-Approval Trials, but will include any other clinical trials of the Licensed Products in the Field in the Territory, including any studies or other activities conducted for Pricing Approval.

1.101 “Territory Development Budget” shall mean the three-year rolling budget(s) approved by the JSC in the Territory Development Plan.

1.102 "Third Party" shall mean any Person other than Company or Regeneron or any Affiliate of either Party.

1.103 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.104 "Valid Claim" shall mean a claim (a) of any issued, unexpired Patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) of any Patent Application that has not been cancelled, withdrawn or abandoned or pending for more than seven (7) years.

1.105 "VEGF" shall mean vascular endothelial growth factor.

1.106 "VEGF Trap" shall mean [*****]

1.107 "Additional Definitions." Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
Aggregate Regeneron Payment Amount	9.2(a)
Alliance Manager	3.2(a)
Collaboration	Preamble
Collaboration Purpose	3.1(b)
Company Products	2.6
Development Budget(s)	5.3
Development Overrun	9.11
Expert Panel	0.4
Global Brand	3.4(b)(i)
Global Development Balance	Schedule 2
Global True-Up	Schedule 2
Governance Dispute	10.2
Initial Development Plan	5.2
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JSC	3.1(a)
Joint Invention	12.1(b)
Manufacturing Cost	Schedule 1
Manufacturing Plan	8.4
Marketing Guidelines	3.4(b)(v)
Non-Approval Trials	6.2(j)

DEFINITION	SECTION/SCHEDULE
Non-Incurred Amount	5.3
Project Manager	3.9
Regeneron Reimbursement Amount	Schedule 2
Quarterly True-Up	Schedule 2
Term	19.1(a)
Termination Notice Period	19.2
Territory Profit Split	Schedule 2
Working Group	3.1(a)

ARTICLE II COLLABORATION

2.1 Scope of Collaboration. The Parties will cooperate in good faith under this Agreement and each Party will use Commercially Reasonable Efforts to Develop Licensed Products in the Field for the purpose of Commercializing Licensed Products in the Field in the Territory. Company will use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory. The Parties shall establish various Committees as set forth in Article 3 of this Agreement to oversee and/or coordinate the Development of Licensed Products in the Field and oversee the Commercialization of Licensed Products in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in Article 16, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to effectively and efficiently Develop and Manufacture Licensed Products in the Field and for Company (and, if agreed to by Company or set forth in the Plans, Regeneron) to effectively and efficiently Commercialize the Licensed Products in the Field in the Territory under this Agreement.

2.2 Compliance With Law. Both Company and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in an effort to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making

of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Existing Licenses and the New Licenses to which it is a party and to notify the other Party of any terms or conditions in any such Existing License or New License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Moreover, each Party shall take all actions reasonably necessary to ensure the other Party's ability to comply with (i) any such Existing License or New License (including any such terms and conditions with which such Party is required to comply as a sublicensee), and (ii) any such material agreement entered into pursuant to a Plan. Neither Party may terminate or amend any Existing License, New License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.

2.5 Plans. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.

2.6 Limitation on Exercise of Rights Outside of Collaboration.

(a) During the Term, except as set forth in this Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Product in the Field in the Territory, except pursuant to this Agreement. For the avoidance of doubt, nothing in the preceding sentence or elsewhere in this Agreement shall limit or restrict either Party's right to research, develop, make, have made, use, sell, offer to sell, have sold, import and export its Products outside the Field, including, without limitation, Regeneron's and Aventis' activities under the Aventis Agreement.

(b) If a Party (the "Proposing Party") presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then the Proposing Party may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the Development Plans; provided, however, the Proposing Party must first present the proposed protocols and clinical trial designs to the other Party for approval, such approval not to be unreasonably withheld or delayed and, for other than

Non-Approval Trials or trials conducted solely for purposes of obtaining Approvals in the Excluded Territory, shall also present to the other Party the related budgets for Clinical Supply Costs and Out-of-Pocket Costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). The other Party's representatives on the JDC may only disapprove any such protocols or clinical trial designs for material safety reasons. If, in compliance with this Section 2.6(b), the other Party does not approve any such protocols or clinical trial designs for material safety reasons, the Proposing Party may not proceed with the proposed clinical trials unless and until the dispute has been resolved as provided in Section 3.10(b) and, if necessary, Section 10.4. In the event that the Proposing Party conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article 4 of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to the Proposing Party with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trials to support an Approval in the Territory, then the other Party shall be required to reimburse the Proposing Party for [*****] of the actual Out-of-Pocket Costs and Clinical Supply Costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to the other Party pursuant to this Section 2.6(b) (if applicable) and the other terms of this Agreement. Nothing in this Section 2.6(b) shall permit Regeneron to make a Registration Filing in the Territory or seek an Approval in the Territory based on any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b), and publication of all data and results thereof shall be subject to Article 16.

(c) If Company determines that one of its or one of its Affiliates' internal product candidates constitutes a Product in the Field or if Company or its Affiliate acquires rights to a Product in the Field in the Territory from a Third Party, Company shall promptly present a proposal to the JDC to include such Product in the Collaboration based on the terms of this Agreement, and, as part of such presentation, shall provide the JDC with all information with respect to such Product reasonably available to Company and material to a decision by Regeneron's representatives on the JDC as to whether to approve the inclusion of such Product in the Collaboration. If Regeneron's representatives on the JDC, in their sole discretion, approve such inclusion of such Product in the Collaboration as a Licensed Product, then such Product shall be included in the Collaboration on the terms of this Agreement (such Products being referred to as "Company Products"). If Regeneron's representatives on the JDC, in their sole discretion, do not approve such inclusion of such Product in the Collaboration, then, for such Products arising from Company's or its Affiliates' internal research and development activities or to which Company or its Affiliates acquire rights, Company or its Affiliates may continue to Develop such Product in the Field in the Territory up to the completion of Phase 2 Trials, at which time Company shall present to Regeneron's representatives on the JDC the available clinical data with respect to such Product for the approval by Regeneron's

representatives on the JDC of inclusion of such Product in the Collaboration as a Licensed Product under the terms of this Agreement. If Regeneron's representatives on the JDC do not, in their sole discretion, approve the inclusion of such Product in the Collaboration on the terms of this Agreement, then Company or its Affiliates may license or otherwise transfer rights to such Product in the Territory in the Field to a Third Party without any further consideration or payments to Regeneron. However, neither Company nor any of its Affiliates may participate in the further Development or Commercialization of such Products in the Field in the Territory. For the avoidance of doubt, any modification, derivative or new formulation of a Regeneron Product Developed by either Party shall be considered a Regeneron Product and not a Company Product.

2.7 Excluded Territory Activities. Notwithstanding that a Company Product or a Regeneron Product is deemed a Licensed Product hereunder, and for the avoidance of doubt, Company shall have the exclusive right and authority, in its discretion, to exploit Company Products in the Field in the Excluded Territory and Regeneron shall have the exclusive right and authority, in its discretion, to exploit Regeneron Products in the Field in the Excluded Territory, in each case, subject only to the terms of this Agreement that expressly apply to Licensed Products in the Field in the Excluded Territory. Each Party agrees to reasonably communicate and consult with the other Party (through the JDC or the other Party's representatives on the JDC, with respect to Development activities, and through the JCC or the other Party's representatives on the JCC, with respect to commercialization activities) on material Development and commercialization activities relating to Licensed Products in the Field in the Excluded Territory. Notwithstanding the foregoing or any other provision in this Agreement, neither Party nor any Committee shall have the right or authority to manage or control the internal operations of the other Party or to approve, modify, impede or delay any of the other Party's commercialization or Development plans or activities for its Products in the Excluded Territory (other than as contemplated under or in connection with the Global Development Plan). Each Party shall reasonably inform the JDC or the JCC or the other Party's representatives on the JDC or JCC, as applicable, of (a) all material clinical and regulatory matters directly relating to its Products in the Excluded Territory, whether or not addressed in the Global Development Plan, and (b) any other Development or commercialization activities directly relating to its Products in the Excluded Territory to the extent such matters or activities would be reasonably expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Territory. To the extent any of the foregoing matters or activities in the Excluded Territory are undertaken pursuant to the Global Development Plan, each Party shall comply with the Global Development Plan; otherwise, the Party Developing and/or commercializing its Product(s) in the Excluded Territory shall consider in good faith all comments of the JDC and the JCC (or the other Party's representatives on the JDC or JCC) with respect to such matters and activities.

**ARTICLE III
MANAGEMENT**

3.1 Committees/Management.

(a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the “JSC”), a Joint Development Committee (the “JDC”), a Joint Commercialization Committee (the “JCC”), a Joint Finance Committee (the “JFC”) and such other Committees as the Parties deem appropriate. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a “Working Group”) to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the “Collaboration Purpose”). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Joint Steering Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Effective Date, the Parties will establish the JSC, which shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program; for the Manufacture of Licensed Products in the Field for use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.10 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager (“Alliance Manager”) to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually

review and approve the Development Plan(s), Manufacturing Plan(s) and Territory Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC as the JSC deems appropriate and (v) consider and act upon such other matters as are specified in this Agreement or otherwise agreed to by the Parties.

3.3 Joint Development Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Effective Date, the Parties will establish the JDC. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the Development of Licensed Products in the Field as part of an integrated worldwide Development program; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Development Plan(s) (and related Development Budget(s)) and (iii) to oversee the implementation of the Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that each Party must appoint, as one of its representatives on the JDC, its Project Manager and provided further, that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) Specific Responsibilities. In particular, subject to Section 2.7, the JDC shall be responsible for:

- (i) advising the JSC on the overall global Development strategy for the Licensed Products in the Field;
- (ii) facilitating an exchange of Development data between the Parties and developing and updating the Development Plans (and related Development Budgets), as described in Sections 5.2 and 5.3, for final approval by the JSC;
- (iii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of, and compliance with, the Development Plans (including the Development Budgets);
- (iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;
- (v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans; advising on material clinical and regulatory matters and other Development activities in the Excluded Territory that are reasonably expected to

materially adversely affect, or have a material impact on, the Development of Licensed Products in the Territory; and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Development Plans and for Non-Approval Trials;

(vi) reviewing and approving proposed target Licensed Product labeling and reviewing, and to the extent set forth herein approving, proposed changes to Product labeling with respect to Licensed Products in the Field in accordance with Section 7.2(f) ;

(vii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;

(viii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;

(ix) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field;

(x) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan; and

(xi) considering and acting upon such other matters as are specified in this Agreement or by the JSC.

3.4 Joint Commercialization Committee.

(a) Formation; Composition and Purpose. Within twenty (20) days after the Effective Date, the Parties will establish the JCC. The purpose of the JCC shall be (i) to develop and propose to the JDC and JSC the strategy for the Commercialization of Licensed Products in the Field in the Territory; (ii) to discuss and advise on certain commercialization activities for the Licensed Products in the Excluded Territory to the extent contemplated in Section 2.7; (iii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Territory Commercialization Plan (and related Territory Commercialization Budget); (iv) to develop (or oversee the development of), review and annually update and approve the Country Commercialization Plans (and related Country Commercialization Budgets) and (v) to oversee the implementation of the Territory Commercialization Plan and the

Commercialization operational aspects of the Collaboration. The JCC shall be composed of at least two (2) senior executives of each Party.

(b) JCC Responsibilities. In particular, subject to Section 2.7, the JCC shall be responsible for:

(i) recommending to the JSC whether a single brand will be used for Commercialization of Licensed Products for one or more indications throughout the Excluded Territory and the Territory ("Global Brand"). If the JCC agrees that a Global Brand(s) for the Licensed Products is desirable, [*****];

(ii) developing and proposing to the JSC the strategy for the Commercialization of the Licensed Products in the Field in the Territory;

(iii) commencing no later than three (3) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing, and updating at least annually, the Territory Commercialization Plans (and related Territory Commercialization Budgets) for final approval by the JSC and (B) approving the Country Commercialization Plan(s) (and related Country Commercialization Budget(s));

(iv) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan for review by the JSC;

(v) developing and updating, as necessary [*****] (collectively, the items referred to in this paragraph (v) shall be referred to as the "Marketing Guidelines") as part of the Territory Commercialization Plan;

(vi) developing target profiles for the Licensed Products in the Field;

(vii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of and compliance with the Territory Commercialization Plans (including the Territory Commercialization Budgets) and Country Commercialization Plans (including the Country Commercialization Budgets), including ensuring that country specific launch plans in the Territory are consistent with the Marketing Guidelines;

(viii) establishing, as necessary, sub-committees of the JCC;

(ix) if the Parties agree to use a Global Brand, selecting a Product Trademark for Licensed Products in the Field in accordance with

Section 11.2 and giving guidance on trade dress in the Field (*****);

(x) if the Parties agree to use a Global Brand, [*****]

(xi) developing and implementing plans and policies regarding journal and other publications with respect to Licensed Products in the Field in concert with the JDC;

(xii) allocating the appropriate cost for Commercialization activities that support the Licensed Products in the Field in the Territory and the Excluded Territory as Other Shared Expenses and/or Shared Promotion Expenses, if applicable, in accordance with this Agreement and assigning responsibilities and approving budgets for such activities;

(xiii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;

(xiv) consulting on all commercialization activities for Licensed Products in the Field in the Excluded Territory that are reasonably expected to materially adversely affect, or have a material impact on, the Commercialization of Licensed Products in the Territory in accordance with, and subject to, Section 2.7 and Section 6.5; and

(xv) considering and acting upon such other matters as are specified in this Agreement or by the JSC or JDC.

3.5 Other Committees. Within ten (10) days after the Effective Date, the Parties will establish the JFC, which shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article 9 and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC and the JCC, as needed.

3.6 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Company. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Company. Each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue draft minutes of each meeting within seven (7) days thereafter and final minutes within thirty (30) days thereafter.

3.7 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than every Quarter during the Term. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of the Products (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Day's prior written notice, except that emergency meetings may be called with at least one (1) Business Day's prior written notice.

3.8 Decision-Making. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.

3.9 Project Manager. Each of Company and Regeneron shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Project Manager ("Project Manager"). Each Project Manager will be responsible for:

(a) coordinating the various functional activities of Company and Regeneron, as appropriate, in developing and executing strategies and Plans for the Licensed Products in the Field in an effort to ensure consistency and efficiency;

(b) providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization regarding key strategy and Plan issues, as appropriate, including facilitating review of external corporate communications; and

(c) identifying and raising cross-country, cross-Party and/or cross-functional disputes to the appropriate Committee in a timely manner.

3.10 Resolution of Governance Matters. As provided in Section 10.2, this Section 3.10 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible:

(i) in the case of any matter which cannot be resolved by the JDC, JCC, JFC or any other committee established by the JSC, at the request of either Party, such matter shall promptly, and in any event within five (5) Business Days (or one (1) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution;

(ii) in the event a unanimous vote on any matter cannot be obtained at the JSC within five (5) Business Days after referral to it pursuant to (i) above, except as set forth in (iii) below, Company shall have the deciding vote with respect to those matters described in [*****] and Regeneron shall have the deciding vote with respect to those matters described in [*****]. Neither Party shall have the deciding vote with respect to matters described in [*****]. For the avoidance of doubt, [*****]

(iii) notwithstanding the above, and subject to Section 7.2(f), if either Party (the “First Party”) [*****] then such dispute shall be resolved in accordance with the dispute resolution procedures set forth in Section 3.10(b); provided, however, that the dispute resolution procedures set forth in Section 3.10(b) shall not apply and the terms of subsection (ii) above shall apply (and thus, the final decision of the Party authorized to cast the deciding vote shall be final and binding on the First Party) if [*****].

(b) Referral to Executive Officers. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, and one Party is not expressly allocated decision making authority over the matter as set forth in this Agreement, then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which, except for Legal Disputes (unless as jointly agreed by the Parties), either Party may by written notice to the other Party require the specific issue in dispute to be submitted for resolution by an Expert Panel pursuant to Section 10.4, if such dispute is with respect to a Technical Development Matter.

(c) Interim Budgets. Pending resolution by the Executive Officers of any referred dispute under Section 3.10(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use

Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.10(c).

(d) Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

ARTICLE IV LICENSE GRANTS

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.5) and any Existing License or New License to which Regeneron is a party, Regeneron hereby grants to Company (a) the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop, import and export Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, subject to Regeneron's right to supply Licensed Products to Company, as contemplated by this Agreement. Company will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.3. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Regeneron is a party, Regeneron also grants to Company the nontransferable (except as permitted by Section 20.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Regeneron Excluded Territory Intellectual Property to make, have made, use, sell, offer to sell, have sold, import or export Company Products for use in the Field in the Excluded Territory.

4.2 Company License Grants. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-exclusive (with Company and its Affiliates) right and license under the Company Intellectual Property to make, have made, develop, use, import and export Licensed Products for use in the Field in the Territory. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company also grants to Regeneron the nontransferable (except as permitted by Section 20.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Company Excluded Territory Intellectual Property to make, have made, use, sell, offer to sell, have sold, import or export Regeneron Products for use in the Field in the Excluded Territory.

4.3 Sublicensing. Unless otherwise restricted by any Existing License or New License, Company will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Company may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any Existing License or New License, Regeneron will have the right to sublicense any of its rights under the first sentence of Section 4.2 only with the prior written consent of Company, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Company's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article 16, and will include, with respect to a Sublicensee of Company, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Company on the same basis as if such sales were Net Sales by Company. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the Territory Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have a materially adverse effect on Regeneron or any of its Affiliates or any Regeneron Intellectual Property, then Regeneron may cause Company or its Affiliate to exercise, and the Company or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and Regeneron, at the option of Regeneron, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Company will forward to Regeneron a complete copy of each fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

4.4 No Implied License. Except as expressly provided in this Article 4 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.5 Retained Rights. With respect to the licenses granted under this Article 4, Regeneron reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, (a) the right to make, have made, distribute, import, export and use Regeneron Products in the Field in the Territory exclusively for Development purposes, and (b) the right to Manufacture and, if agreed to by Company or set forth in any Plans, the right to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Regeneron retains all rights in Regeneron

Intellectual Property, Regeneron's interest in the Joint Inventions and Regeneron Products not expressly licensed hereunder, including, without limitation the right (i) to exploit Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions to make, have made, use, sell, offer to sell, have sold, import or export Products for use outside the Field; (ii) to exploit Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions to make, have made, use, sell, offer to sell, have sold, and import and export Products for use in the Field in the Excluded Territory and (iii) to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

4.6 Right of Negotiation for Excluded Territory. In the event that Regeneron desires to enter into a license or co-promotion arrangement with a Third Party (other than with an Affiliate, distributor or contract sales force) with respect to commercialization of the Regeneron Products in the Excluded Territory, Regeneron shall grant Company a first right of exclusive negotiation for such commercialization rights. If Regeneron desires to enter into such a commercialization arrangement, Regeneron shall give Company written notice. Company shall have [*****] to determine and to notify Regeneron in writing whether Company desires to negotiate such a commercialization arrangement. Failure to provide written notice to Regeneron within such [*****] period shall be deemed to be a rejection of Regeneron's offer to negotiate for such commercialization rights. If Company rejects Regeneron's offer to negotiate for such commercialization rights, or if Company accepts Regeneron's offer to negotiate for such commercialization rights but the Parties are unable to reach an agreement on such commercialization arrangement, after negotiating in good faith, within [*****] of the date Regeneron notified Company of its desire to enter into such commercialization arrangement, then Regeneron shall have no further obligation to Company with respect to the Regeneron Products in the Excluded Territory.

ARTICLE V DEVELOPMENT ACTIVITIES

5.1 Development of Licensed Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices. Regeneron may conduct separate Development activities to support Regeneron Products in the Excluded Territory, and Company may conduct separate Development activities to support Company Products in the Excluded Territory, in each case, subject to the conditions and requirements set forth herein, including, without limitation, Section 2.6(b).

5.2 Development Plans. The JDC shall prepare and update Development Plans for Licensed Products in the Field under this Agreement for approval by the JSC. Except for the first Global Development Plan incorporating the Initial Development Plan referred to below in this Section 5.2, an updated Global Development

Plan (and, if applicable, Territory Development Plan) will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Development Plan will set forth the plan for Development of each Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for the Licensed Products in the Field in the Territory and, subject to Section 2.7, the Excluded Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers to the extent provided by the applicable Development Plan. Each Development Plan will be reviewed and informally updated by the JDC not less frequently than every six (6) months for the ensuing three (3) year period. The activities agreed to by the Parties (together with the associated estimated budget) as set forth on Schedule 5 shall constitute the initial plan for the Development of Licensed Products in the Field under this Agreement (the “Initial Development Plan”). No later than sixty (60) days after the Effective Date, the JDC will meet to finalize the first Global Development Plan (which, as provided above, shall incorporate, or be substantially consistent with, the Initial Development Plan). Until the first Global Development Plan is approved by the JSC, the Parties will Develop the Licensed Products in the Field under this Agreement in accordance with the Initial Development Plan, unless otherwise agreed to by the JSC. Unless otherwise agreed to by the JDC, each update to the Development Plan(s) shall include the activities and timelines described in or referred to in the Initial Development Plan until the activities described therein are completed in a timely manner.

5.3 Development Budgets. The Territory Development Plan shall include the Territory Development Budget and the Global Development Plan shall include the Global Development Budget (each individually, a “Development Budget” and both collectively, the “Development Budgets”) and the Development Budgets shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Development Plans in accordance with this Agreement. Amendments and updates to any Development Budgets shall not be effective without the approval of the JSC. In the event that, during any Contract Year (the “First Year”), any Development activity expressly provided for in the approved Development Budget to be completed during such First Year is not completed during such First Year (to the extent incomplete, an “Incomplete Activity”) and the full expense budgeted for such activity for such First Year is not incurred (to the extent not incurred, a “Non-Incurred Amount”), then such Incomplete Activity shall be completed during Contract Years following such First Year (the “Succeeding Year(s)”) and the Non-Incurred Amount shall be included in the Development Budget for such Succeeding Year(s) as set forth in the following sentence. If the Development Budget for such Succeeding Year(s) has not yet been approved by the JSC, then the Non-Incurred Amount shall be included in the proposed Development Budget for such Succeeding Year(s) without otherwise limiting any other Development activities or any amounts related thereto, unrelated to the Incomplete Activity, which, pursuant to the Development Plan, would have been performed during such Succeeding Year, and if the Development Budget for the Succeeding Year(s) has been approved by the JSC, then the Development Budget for such Succeeding Year(s) shall be revised automatically to include the Non-Incurred Amount.

5.4 Development Reports. Within forty-five (45) days after the end of each Quarter, Regeneron and Company shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter and shall be in such form, format and of such level of detail as approved by the JFC. At the next JDC meeting held following such forty-five (45) day period, the JDC will approve the final Development Costs which will be used in the calculation of the Global Development Balance.

5.5 Review of Clinical Trial Protocols. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by either Party pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials meeting established criteria. In no event will such procedures require more than ten (10) Business Days for the JDC to accept or reject a proposed protocol and/or clinical trial design for a clinical study to be conducted solely for purposes of obtaining an Approval in the Excluded Territory.

ARTICLE VI COMMERCIALIZATION

6.1 Commercialization of Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC and in accordance with the Territory Commercialization Plan and the Country Commercialization Plans. Except as set forth in this Agreement, Company shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory.

6.2 Territory Commercialization Plan. The Territory Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Territory Commercialization Plan will be prepared by Company, with Regeneron's participation and input with respect to the portions of such Plan directly applicable to the Major Market Countries, and submitted to the JCC for review and approval. Once approved by the JCC, the Territory Commercialization Plan will be presented to the JSC for review and approval at least [*****] before the Anticipated First Commercial Sale in the Territory. The Territory Commercialization Plan for each subsequent Contract Year shall be updated by the JCC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year. Each Territory Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall strategy for Commercializing Licensed Products in the Field in the Territory, including Licensed Product target product profiles, branding, positioning, promotional materials and core messages;
 - (b) subject to applicable Law, Licensed Product pricing guidelines in the Field in the Territory;
 - (c) the Territory Commercialization Budget;
 - (d) anticipated launch dates for applicable countries in the Territory;
 - (e) any global Commercialization activities that are designed to benefit the Licensed Product in the Field in both the Territory and the Excluded Territory (including, without limitation, such activities that relate to global branding, global market research, Licensed Product websites and certain publication strategies);
 - (f) market and sales forecasts for the Licensed Products in the Field in the Territory in a form to be agreed between the Parties;
 - (g) strategies for the detailing and promotion of Licensed Products in the Field in the Territory, including recommended sales force sizes in the countries in the Territory;
 - (h) anticipated major advertising, public relations and patient advocacy programs for Licensed Products in the Field in the Territory;
 - (i) reimbursement and patient assistance, including [*****];
 - (j) post-marketing clinical trials to support Commercialization of Licensed Products in the Field in the Territory which [*****], including any such clinical trials sponsored by Third Parties using Licensed Product supplied by the Parties (“Non-Approval Trials”);
 - (k) proposed use of Third Party sales representatives, Sublicensees and/or distributors in any country in the Territory;
 - (l) target incentive product weighting and performance goals for sales representatives detailing the Licensed Products in the Field in the Territory;
- and
- (m) all other Marketing Guidelines.

6.3 Country Commercialization Plans. Each Country Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Country Commercialization Plan for each Major Market Country will be prepared by Company, with Regeneron’s participation and input, and approved by the JCC at least [*****] before the Anticipated First Commercial Sale in the applicable Major Market Country. The Country

Commercialization Plan for each subsequent Contract Year shall be updated and approved by the JCC at least two (2) months prior to the end of the then current Contract Year. Each Country Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall strategy for Commercializing Licensed Products in the Field in the Major Market Country, including Licensed Product branding, positioning, promotional materials, core messages, pricing strategies and competitive analyses;
- (b) the Country Commercialization Budget;
- (c) anticipated launch dates for the Licensed Product in the Field in the Major Market Country;
- (d) market and sales forecasts for the Licensed Products in the Field in the Major Market Country in a form to be agreed between the Parties;
- (e) strategies for the detailing and promotion of Licensed Products in the Field in the Major Market Country, including sales force and medical affairs field force sizes, the number and type of Licensed Product details to be performed by Company sales representatives and target opinion leaders in the Major Market Country;
- (f) FTE requirements and Shared Promotion Expenses to fulfill the requirements of the Country Commercialization Plan;
- (g) advertising, patient advocacy programs, professional symposia, public relations, marketing, sales and promotion efforts for Licensed Products in the Field in the Major Market Country;
- (h) reimbursement and patient assistance, including [*****]; and
- (i) Non-Approval Trials (based on JDC approved protocols), [*****] in support of the Licensed Products in the Field in the Major Market Country.

6.4 Commercialization Activities; Sharing of Commercial Information.

(a) Company (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Territory Commercialization Plan and the Country Commercialization Plans. Without limiting the foregoing, Company will, as necessary, build, train and apply a field force in the Territory necessary to

Commercialize the Licensed Products in the Field in the Territory in accordance with the Territory Commercialization Plan and Country Commercialization Plans.

(b) Company will use reasonable efforts to provide Regeneron with full access to Company information directly relating to the Commercialization of the Licensed Products in the Field in the Territory, including, without limitation, information relating to anticipated launch dates, the development of sales targets by customer segment and territory, key market metrics, market research, sales forecasting and modeling, sales, prescription and patient data, reimbursement and pricing matters, and field force plans, goals, incentives and training.

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information from the Territory or the Excluded Territory, as the case may be.

(d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.

6.5 Product Pricing and Pricing Approvals in the Territory. [*****]. For the avoidance of doubt,

(i) Regeneron shall have sole authority for determining and establishing the price and terms of sale (including any rebates or discounts) of Regeneron Products in the Excluded Territory and Company shall have sole authority for determining and establishing the price and terms of sale (including any rebates or discounts) of Company Products in the Excluded Territory.

6.6 Sales and Product Distribution in the Territory; Other Responsibilities. Company (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Company (or its Affiliate) also shall be responsible for (a) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (b) handling all returns of Licensed Product sold under this Agreement and (c) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory. If Licensed Product sold in the Field in the Territory is returned to Regeneron, it shall promptly be shipped to a facility designated by Company. If Regeneron Product sold in the Excluded Territory is returned to Company, it shall promptly be shipped to a facility designated by Regeneron. If Regeneron receives an order for Licensed Product in the Field in the Territory (or Company receives an order for Regeneron Product in the Field in the Excluded Territory), the Party erroneously receiving the order shall refer such orders to the other Party.

6.7 Commercialization Efforts. Company's sales representatives in the Territory shall provide the FTE effort and promote and detail the Licensed Products in the Field in accordance with the approved Country Commercialization Plan (if applicable), Territory Commercialization Plan and all applicable Laws. Company shall, at its own expense, comply with the training plan contained in any Country Commercialization Plan.

Beginning in the Quarter of the First Commercial Sale in each Major Market Country, Company will provide Regeneron on a quarterly basis with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Company for its internal management purposes. Company (through its local Affiliates where appropriate) shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the determination of Sales Force Cost and Medical Affairs Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

6.8 Contract Sales Force. Company shall not use the services of a sales representative employed by a Third Party without Regeneron's prior written consent. Company will be responsible for (a) all costs associated with retaining any such contract sales force in excess of the expected Sales Force Cost if Company provided its own field force and for such Third Party's compliance with this Agreement, (b) ensuring such contract sales force's compliance with all applicable Laws and (c) ensuring that sales representatives in such contract sales force have minimum skill levels customary for sales representatives in the Field at major pharmaceutical companies in such country.

6.9 Promotional Materials.

(a) Company will be responsible, consistent with the Marketing Guidelines, the Territory Commercialization Plan and the Country Commercialization Plans (as applicable), 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 Territory. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Company for use in the Territory. (b) Company shall use its own corporate name and/or logo on Promotional Materials and Licensed Product labels in connection with Commercialization of Licensed Products in the Territory, unless otherwise mutually agreed by the Parties.

(b) The Parties shall jointly own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.

6.10 Promotional Claims/Compliance. Neither Company nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), Company and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.

6.11 Restriction on Bundling in the Territory. If Company or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Company agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed

Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer or (b) is inconsistent with the Collaboration Purpose.

6.12 Inventory Management. Company shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.13 Medical and Consumer Inquiries. Company shall be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Licensed Products in the Field in the Territory. The Parties will work together to formulate responses to the major inquiries, which shall be used, if possible, by Company in the Territory and Regeneron in the Excluded Territory. If Regeneron receives questions about Licensed Products in the Field in a country in the Territory, it shall refer such questions to Company, and Company shall be responsible for responding thereto. If Company receives a question about Regeneron Products in the Field in a country in the Excluded Territory (or about any Regeneron Product outside the Field), it shall refer such questions to Regeneron, and Regeneron shall be responsible for responding thereto.

6.14 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Product in the Field may be marketed in such country.

6.15 Post Marketing Clinical Trials. Subject to the provision of this Agreement, the Parties shall comply with any clinical trial obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

6.16 Activities outside the Collaboration. During the Term, neither Party nor any of its respective Affiliates, either alone or through any Third Party, shall Develop or Commercialize a Product in the Field in the Territory except as set forth in this Agreement. In the event that (a) Regeneron terminates this Agreement for any reason or (b) Company terminates this Agreement for any reason other than pursuant to Section 19.3 or Section 19.4, then [*****], Company (nor its Affiliates or Sublicensees) shall not, directly or indirectly, Commercialize any Products in the Field in any part of the Territory. In the event that Company terminates this Agreement pursuant to Section 19.3 or Section 19.4, [*****] Regeneron (nor its respective Affiliates or Sublicensees under this Agreement) shall not, directly or indirectly, Commercialize any Products in the Field in any part of the Territory other than Regeneron

Products as to which, as of the date notice of such termination is received by Regeneron, Regeneron has ownership of, or a license to. A Party shall not be considered in breach of this Section 6.16 solely by reason of the acquisition by such Party of a Person (i) if such Party includes the offending Product(s) in the licenses granted to the other Party pursuant to this Agreement or (ii) if prior to the closing of such acquisition, the acquiring Party commits in writing to the other Party that, promptly following the closing of such acquisition, it will divest itself of the offending rights and/or activity, and the acquiring Party uses Commercially Reasonable Efforts to pursue such divestiture, and in the event that such divestiture is not completed within six (6) months of the closing of such acquisition, the acquiring Party ceases all Development, Manufacturing and/or Commercialization, as applicable, of the offending Product(s) in the Field or includes the offending Products(s) in the licenses granted to the other Party pursuant to this Agreement.

6.17 Restriction on Commercialization Activities. Company agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing Regeneron Products outside the Field, and, in particular, engaging in any advertising, promoting or marketing of Regeneron Products aimed at uses outside the Field. Without limiting the foregoing, it is agreed that the Parties shall use Commercially Reasonable Efforts to [*****] and each Party shall use Commercially Reasonable Efforts to [*****]. Company further agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing Licensed Products that it is Commercializing hereunder in the Field in the Territory for sale in the Excluded Territory. Each Party will use reasonable efforts to prevent the unauthorized importation of Licensed Products into the Territory or Excluded Territory, as the case may be.

6.18 Exports from the Territory to the Excluded Territory.

(a) Company shall supply the [*****] with Licensed Products in quantities that are appropriate to the size of such market (not including cross-border sales).

(b) The Parties shall discuss, as appropriate from time to time, through their respective representatives on the JSC, any concerns either Party may have with respect to the entry of Licensed Products into the Excluded Territory from the Territory, including [*****] (“Parallel Trade Concern”).

(c) No later than ninety (90) days after Regeneron raises a Parallel Trade Concern, the Parties hereby agree to negotiate in good faith to determine a method for the calculation of [*****] (the “Parallel Unit Sales”). Such Parallel Unit Sales shall be determined based on available data, as agreed by the Parties, measuring [*****]. Out-of-Pocket Costs associated with obtaining the data required to meet Company’s obligations hereunder shall be treated as Shared Promotion Expenses.

(d) Within fifteen (15) days after the end of any Contract Year in which Regeneron raises a Parallel Trade Concern, Company shall provide a detailed written report, which shall include copies of all data used to generate such report (the "Parallel Trade Report"), to Regeneron. The Parallel Trade Report shall [*****]

(e) Promptly following delivery of the Parallel Trade Report, the Parties will meet and make a good faith effort to agree upon [*****]

(f) Notwithstanding anything to the contrary contained herein, nothing contained in this Section 6.18 shall require any Party to take actions inconsistent with applicable Law.

**ARTICLE VII
CLINICAL AND REGULATORY AFFAIRS**

7.1 Ownership of Approvals and Registration Filings.

(a) Regeneron shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Development of Regeneron Products in the Field in the Excluded Territory under the Global Development Plan and (ii) with respect to any site license for its manufacturing facilities anywhere in the world, and shall have the rights and obligations set forth in this Article 7 with respect thereto.

(b) During the Term, Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Licensed Products in the Field in each country in the Territory and (ii) with respect to any site license for its manufacturing facilities anywhere in the world, and shall have the rights and obligations set forth in this Article 7 with respect thereto. Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, for any Company Products in the Field in the Excluded Territory with respect to the Development of Company Products under a Global Development Plan.

(c) The Lead Regulatory Party shall, as reasonably necessary to permit a Party to perform obligations under this Agreement, license, transfer, provide a letter of reference with respect to or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the Licensed Product in the Field in each jurisdiction as to

which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article 7. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for the Licensed Products in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.

(b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities, (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the world, including the Excluded Territory, and (iii) to comply with Laws with respect to the development, manufacture and/or commercialization of Products outside the Field. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory, and, subject to Section 2.7, with respect to the same in the Excluded Territory to the extent that such strategies, actions, and/or communications would reasonably be expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Field in the Territory.

(c) Subject to Sections 2.7 and 7.2(f), the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities that directly pertain to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including, without limitation, all annual and periodic safety reports for Licensed Products in the Field). Moreover, the Lead Regulatory Party shall consider in good faith requests from the other Party to have up to two (2) representatives from the other Party attend (but not participate) in all material, pre-scheduled meetings, telephone conferences and/or discussions with the Regulatory Authorities in the Territory or, to the extent such material meetings, telephone conferences and/or discussions pertain to the activities under the Global Development Plan, the Excluded Territory. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The

Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

(d) For the avoidance of doubt, nothing in this Section 7.2 entitles Company to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Regeneron Products in the Excluded Territory, except as they relate to the performance of the Global Development Plan. Subject to its obligations hereunder, Regeneron, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the Commercialization of Regeneron Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit, any Registration Filings for Marketing Approval for a Regeneron Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Regeneron Product.

(e) For the avoidance of doubt, nothing in this Section 7.2 entitles Regeneron to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Company Products in the Excluded Territory, except as they relate to the performance of the Global Development Plan. Subject to its obligations hereunder, Company, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the Commercialization of Company Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit any, Registration Filings for Marketing Approval for a Company Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Company Product.

(f) [*****].

7.3 Regulatory Coordination with Third Parties. Regeneron shall use Commercially Reasonable Efforts under the Aventis Agreement (a) to allow Company and its Affiliates to reference the filings, registrations, licenses and authorizations from or with any Regulatory Authority in connection with Regeneron's and Aventis' development, manufacture and commercialization of Products outside the Field to support the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory under this Agreement and (b) to coordinate the exchange of information (including, without limitation, information pertaining to pharmacovigilance, development, manufacture and commercialization) related to Licensed Products inside and outside the Field between Regeneron, Company and Aventis (or any other Third Party licensee of Regeneron engaged in the development, manufacture and/or commercialization of Licensed Products outside the Field) in order to ensure compliance with applicable Laws. It is agreed that (i) Regeneron and its Affiliates and licensees of Regeneron Products outside the Field (including, without limitation, Aventis) or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the

Regeneron Products to support their development, manufacture and commercialization of Regeneron Products outside the Field or outside the Territory and (ii) Company and its Affiliates and licensees of Company Products outside the Field or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the Company Products to support the development, manufacture and commercialization of Company Products outside the Field or outside the Territory. Company and Regeneron shall work in good faith to coordinate the exchange of information (including, without limitation, pharmacovigilance information) related to Products inside and outside the Field (and inside and outside the Territory) between Regeneron, Company and Aventis (or any other Third Party licensee of a Party engaged in the development, manufacture and/or commercialization of Products outside the Field or outside the Territory) in order to ensure compliance with applicable Laws. As between the Parties, Regeneron shall have the exclusive right to communicate with Regulatory Authorities with respect to Regeneron Products outside the Field and, subject to Section 2.7, in the Excluded Territory, and Company will have the exclusive right to communicate with Regulatory Authorities with respect to Company Products outside the Field and, subject to Section 2.7, in the Excluded Territory.

7.4 Regulatory Events. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority in the Territory or Excluded Territory, which:

(a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field in the Territory.

Information that shall be disclosed pursuant to this Section 7.4 shall include, but not be limited to:

(i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the

extent involving matters described in clauses (a), (b) or (c) of this Section 7.4;

(iii) receipt of a warning letter issued by a Regulatory Authority;

(iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and

(v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).

7.5 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints for its territory and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning drug safety surveillance and product complaint reporting in all countries in which the Licensed Products (both in the Field and out of the Field) are being developed, manufactured, or commercialized in the Territory or in the Excluded Territory. Without limitation to the foregoing, the Parties shall within ninety (90) days of the Effective Date execute a Pharmacovigilance Agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse drug experiences and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.

7.6 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

7.7 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

ARTICLE VIII MANUFACTURING AND SUPPLY

8.1 Formulated Bulk Product Supply in the Field in the Territory. Subject to Regeneron's obligations under the Aventis Agreement, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements of Regeneron Product in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Company's prior written approval, such approval not to be unreasonably withheld or delayed, Company or Third Parties to Manufacture such Formulated Bulk Product. [*****.] The Formulated Bulk Product Manufactured by or on behalf of Regeneron will be billed to Company by Regeneron at the Manufacturing Cost.

8.2 Finished Product Supply in the Field in the Territory. The Parties, through the JSC, will identify which Party or Third Party will perform the filling, packaging, labeling and testing of the Formulated Bulk Product to supply Finished Product for Clinical Supply Requirements and Commercial Supply Requirements for use in the Field under this Agreement. The Finished Product Manufactured by or on behalf of a Party will be billed at the Manufacturing Cost to the other Party as a Development Cost or Commercial Supply Cost, as the case may be, in accordance with Schedule 1.

8.3 Supply Agreement. Within six (6) months after the Effective Date, the Parties shall enter into one or more clinical supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements, which shall contain terms consistent with this Agreement. At least [*****] prior to the Anticipated First Commercial Sale, the Parties shall enter into separate commercial supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements and Commercial Supply Requirements after the First Commercial Sale, which shall contain terms consistent with this Agreement. Each supply agreement will include as an annex thereto a customary quality agreement containing terms and conditions regarding quality

assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

8.4 Manufacturing Plans. The Parties, through the JSC, will develop and update as necessary, the Licensed Product Manufacturing plan (the “Manufacturing Plan”) providing for the Manufacturing (including testing and specifications), distribution, and forecasting of Clinical Supply Requirements under the Development Plans and Commercial Supply Requirements under the Territory Commercialization Plan, including, if applicable, the choice of Third Party manufacturers, fillers, packagers, and labelers. However, Regeneron will have the right to make all decisions with respect to Manufacturing Formulated Bulk Product for Regeneron Products, subject to Company’s prior written approval, such approval not to be unreasonably withheld or delayed. Each Manufacturing Plan shall set forth the Licensed Product requirements over an ensuing period of at least three (3) Contract Years. The Manufacturing Plan will include [*****]. The Manufacturing Plan (including each annual update thereto) shall be approved by the JSC at least two (2) months prior to the end of the then current Contract Year, except that the initial Manufacturing Plan shall be approved by the JSC within four (4) months after the Effective Date. The Parties shall design Manufacturing Plans to ensure an adequate supply of Licensed Product and shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the approved Manufacturing Plans.

8.5 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product should be utilized. In case of Finished Product or Formulated Bulk Product shortages, available supplies will be allocated as between the Parties on a pro rata basis based on their forecasted requirements for Licensed Product in the Field in the Territory and the Excluded Territory over the relevant period; provided that priority shall be given to meeting supply requirements for countries in which Licensed Products are in the launch phase and that, if the shortage is due solely to a breach by Regeneron, Company’s (and, if applicable, Regeneron’s) reasonable requirements under the Plans will be filled first in advance of filling requirements for the Excluded Territory.

8.6 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article 8 or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party’s facilities involved in the Manufacture of Licensed Products in the Field pursuant to

this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Aventis, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

**ARTICLE IX
PERIODIC REPORTS; PAYMENTS**

9.1 Upfront Payment and Milestone Payments.

(a) Within five (5) Business Days of the Effective Date, Company will pay to Regeneron the non-refundable, non-creditable amount of US \$75,000,000 (which shall not be reduced by any withholding or similar taxes).

(b) In addition to the other payments contemplated herein, Company shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Company shall have five (5) Business Days from the receipt of an invoice from Regeneron related to the achievement of any such milestone to pay the corresponding amount to Regeneron, which, in each case, shall not be reduced by any withholding or similar taxes.

9.2 Development Costs.

(a) Regeneron shall be responsible for paying one hundred percent (100%) of the Development Costs incurred by it under the Global Development Plan in 2006. In 2007, (i) the Parties shall each pay fifty percent (50%) of the Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan up to a total of US \$50,000,000, and (ii) Regeneron shall pay one hundred percent (100%) of Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan in excess of US \$50,000,000, up to the amount budgeted for 2007 in the Initial Development Plan. In 2008, (i) the Parties shall each pay fifty percent (50%) of the Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan, up to a total of US \$70,000,000, and (ii) Regeneron shall pay one hundred percent (100%) of Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan in excess of US \$70,000,000, up to the amount budgeted for in 2008 in the Initial Development Plan (such amount paid by Regeneron pursuant to this clause (ii), together with the amount paid one hundred percent (100%) by Regeneron in 2007 pursuant to clause (ii) in the preceding sentence, being referred to as the "Aggregate Regeneron Payment Amount"). Notwithstanding the foregoing, [*****]. Commencing on January 1, 2009 and continuing during the Term, each of Company and Regeneron shall be responsible for paying fifty percent (50%) of all Development Costs incurred under the Global

Development Plan in accordance with the terms of this Agreement by or on behalf of Company, Regeneron and their respective Affiliates.

(b) Commencing on the Effective Date and continuing during the Term, Company shall be responsible for paying one hundred percent (100%) of the total Development Costs incurred under the Territory Development Plan in accordance with the terms of this Agreement by or on behalf of Company, Regeneron and their respective Affiliates.

(c) If Company desires to use efficacy data from a clinical trial conducted by or on behalf of Regeneron in the Excluded Territory (and outside the scope of the Global Development Plan) to support an application for Marketing Approval (including a new label claim) for a Licensed Product in the Field in the Territory, such trial shall be deemed to be part of the Global Development Plan and Company shall reimburse Regeneron for [*****] of the Development Costs incurred by Regeneron in connection with such trial, provided such clinical trial was previously presented to Company for inclusion in the Global Development Plan pursuant to Section 2.6(b). Nothing in this subsection (c) will require Company to reimburse Regeneron for such costs if the data is used solely as part of an annual report, periodic safety report or other regular filing required by a Regulatory Authority in the Territory or applicable Laws.

(d) If Regeneron desires to use efficacy data from a clinical trial conducted by or on behalf of Company pursuant to a Territory Development Plan to support an application for Marketing Approval (including a new label claim) for a Regeneron Product in the Field in the Excluded Territory, such trial shall be deemed to be part of the Global Development Plan and Regeneron shall reimburse Company for [*****] of the Development Costs incurred by Company in connection with such trial, provided such clinical trial was previously presented to Regeneron for inclusion in the Global Development Plan pursuant to Section 2.6(b). Nothing in this subsection (d) will require Regeneron to reimburse Company for such costs if the data is used solely as part of an annual report, periodic safety report, or other regular filing required by a Regulatory Authority in the Excluded Territory or applicable Laws.

9.3 Periodic Reports. Company and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;

(b) Within twenty (20) days following the end of each month, Company shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;

(c) Within forty-five (45) days following the end of each Quarter, Company shall deliver electronically to Regeneron a written report setting forth,

on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;

(d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses incurred by such Party in such Quarter, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;

(e) Within forty-five (45) days after the end of each Quarter commencing after the First Commercial Sale in a country in the Territory (or such earlier agreed upon calendar Quarter, if appropriate), Company shall provide to Regeneron, in electronic form, a Country Commercialization Report for each country in the Territory.

(f) Within forty-five (45) days following the end of each Quarter commencing after the First Commercial Sale in the Territory (or such earlier agreed upon calendar Quarter, if appropriate), each Party that has incurred any Shared Promotion Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Shared Promotion Expenses incurred by such Party in such Quarter;

(g) Within forty-five (45) days following the end of each Quarter, each Party (if applicable) shall deliver electronically to the other Party a written report setting forth Commercial Supply Costs incurred by such Party for such Quarter; and

(h) Within sixty (60) days following the end of each Quarter, Company shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article 9 and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.4 and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.3 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.4 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Company is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section 9.10, make such payment to Regeneron within ten (10) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section

9.10, make such payment to Company within ten (10) days after its receipt of such Consolidated Payment Report from Company. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Company shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any Existing License or New License (to the extent attributable to the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such Existing License and/or New License, as the case may be.

9.5 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.

9.6 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 United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars at the average rate of exchange for the Quarter to which such payment relates, as reported in *The Bloomberg Professional*, a service of Bloomberg LP, or in the event *The Bloomberg Professional* does not have data available for the Quarter, then in *The Wall Street Journal* and by a method of conversion consistent with Company's customary and usual procedures used for currency conversion in its financial statements.

9.7 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus [*****] (such sum being referred to as the "Default Interest Rate").

9.8 Taxes. Except with respect to the payments provided for in Section 9.1, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, Company agrees to make all lawful and reasonable efforts

to minimize any such taxes, assessments and fees and will claim on Regeneron's behalf the benefit of any available Treaty on the Avoidance of Double Taxation that applies to any payments hereunder.

9.9 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party (such request to occur not more than once every three (3) years for any country), the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Sales Force FTE Rate, Medical Affairs FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.10 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this Article 9, 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. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.10(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

9.11 Budget Overruns. Notwithstanding anything to the contrary in this Agreement (including Section 3.10(a)(ii)), neither Party shall be required (a) to pay any Development Costs that are in excess of [*****] of the total amounts that are in the JSC approved Global Development Budget (or Territory Development Budget) for a Contract Year ("Development Overruns") or (b) to pay any Shared Promotion Expenses that are in excess of [*****] of the total amounts that are in the JSC approved Territory Commercialization Budget (or Country Commercialization Budget) for a Contract Year ("Commercialization Overruns"), unless such Development Overruns or Commercialization Overruns have been approved by both Parties' representatives on the JSC. Otherwise, the Party responsible for the Development and/or Commercialization activities that caused the overrun shall be responsible for bearing those costs and expenses, or, if both Parties contributed toward the overrun, they shall bear those excess expenses in the same proportion as their contributions to the overrun. Any such Development Overruns or Commercialization Overruns that are not approved by both Parties' representatives on the JSC shall not be included in the calculation of the Regeneron Reimbursement Amount, Global True-Up, Global Development Balance or Territory Profit Split, as applicable. For clarity, the Parties shall share, to the extent provided in this Agreement, Development Costs and Shared Promotion Expenses that are over the budgeted amounts in the Plans up to [*****] of the budgeted amounts.

ARTICLE X
DISPUTE RESOLUTION

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article 3 ("Governance Disputes") shall be resolved pursuant to Article 3 and, to the extent such matters constitute Technical Development Matters or a dispute referred to in Section 14.2(b), Section 10.4 (subject to, and without limitation of, the proviso in Section 3.10(a)(iii)), except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "Technical Development Matter" shall mean (a) any matter involving the Development of a Licensed Product in the Field, including the determination of clinical trial design and any Development or regulatory dispute referred to the Executive Officers pursuant to Section 3.10(a)(iii) and (b) any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).

10.3 Legal Disputes. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.10(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.

10.4 Expert Panel

(a) In the event of a dispute between the Parties concerning a Technical Development Matter or a dispute referred to in Section 14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.10(b) (other than a Legal Dispute or any dispute concerning any proposed amendment to the Initial Development Plan), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4. Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. For disputes referred to the Expert Panel arising under Section 3.10(a)(iii), the Expert Panel in resolving the dispute shall balance the relative benefits and harm to each Party from the matter in dispute in connection with the applicable

Licensed Product in the Territory and Excluded Territory. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.

(b) Within fifteen (15) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

(c) Within fifteen (15) days of the appointment of the second expert, the two-appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.

(d) Within seven (7) days of the appointment of the third expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel

agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution.

(e) In rendering the final decision (which shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.

10.5 No Waiver. Nothing in this Article 10 or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory and in the Excluded Territory, if applicable pursuant to Section 3.4(b)(i), unless such Product Trademark is prohibited by law in any country in the Territory. Each Licensed Product in the Field shall be promoted and sold in the Territory, and if applicable pursuant to Section 3.4(b)(i) in the Excluded Territory, under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Company (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory. It is understood and agreed that Regeneron shall own and retain all right, title and interest in the Product Trademark(s) for Regeneron Products,

together with all associated domain names and all goodwill related thereto in the Excluded Territory.

11.4 Prosecution and Maintenance of Product Trademark(s). Company will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Company elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Regeneron shall have the right to do so on behalf of Company for use with Licensed Products, subject to consultation and cooperation with Company.

11.5 License to the Product Trademark(s). Company hereby grants to Regeneron a co-exclusive license to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if agreed to by Company or set forth in any Plans, Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Company shall utilize the Product Trademark(s) only on approved Promotional Materials or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Company or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.

11.6 Use of Corporate Names. Company (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials exclusively related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product) in the Major Market Countries, unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field in the Major Market Countries as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and for a maximum period of three (3) years thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples solely to the extent necessary to exhaust the existing inventory of Licensed Product and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each

such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

ARTICLE XII NEWLY CREATED INVENTIONS

12.1 Ownership of Newly Created Intellectual Property.

(a) Each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Company, its Affiliates, employees, agents and consultants are referred to herein as "Company Sole Inventions." Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Company or its Affiliate (or for which ownership vests in Company or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole ("Joint Inventions").

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article 4, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article 12 shall relieve a Party or its Affiliates of their obligations under Article 16 with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory and shall confer with and keep Company reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents in the Territory included in the Regeneron Patent Rights: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Company for review and comment a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and consider in good faith any comment from Company; (ii) Regeneron shall provide Company promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Company promptly

following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications and (iv) Regeneron shall consult with Company a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Company of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and, subject to any rights granted to Aventis under the Aventis Agreement, Company shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Regeneron's name, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Company that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret.

(b) Company shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Company Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Company shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents in the Territory included in the Company Patent Rights: (i) Company shall use Commercially Reasonable Efforts to provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Company and consider in good faith any comment from Regeneron; (ii) Company shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Company shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications and (iv) Company shall consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Company desires to abandon any Patent included in the Company Patent Rights in the Territory, Company shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Company Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Company's name, unless, with respect to any such Patent Applications that are unpublished, Company notifies Regeneron that

Company would prefer to maintain the subject matter of such Patent Application as a trade secret.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall use Commercially Reasonable Efforts to provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and consider in good faith any comment; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications

pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Company Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Company Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be shared by the Parties as part of Other Shared Expenses.

12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Company Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. 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, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Patent Rights, by Company in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties. Regeneron may have certain obligations under Section 12.3 of the Aventis Agreement with respect to any such proceeding described in this Section 12.3(a) and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Company Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be shared by the Parties as part of Other Shared Expenses.

ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual or suspected infringement of a Company Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property

right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any such actual or suspected infringement described in this Section 13.1 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) With respect to any infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Patent Rights, by Company in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party". The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall be shared equally by the Parties, subject to any obligations under any New License or Existing License.

(c) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) related to activities in the Field in the Territory shall be shared by the Parties as part of Other Shared Expenses.

(d) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent.

13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

13.3 Third Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any allegation described in this Section 13.3 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be shared by the Parties as Other Shared Expenses.

(c) For the avoidance of doubt, neither Party will enter into any settlement of any suit involving Licensed Products that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.

(d) License fees, royalties and other payments under Existing Licenses and New Licenses to the extent attributable to, and based on, the Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be shared by the Parties as Other Shared Expenses.

ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its costs), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent “Big Four” (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, 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 no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) 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 within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article 10. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than ten percent (10%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 16.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 GAAP/IAS/IFRS. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with GAAP or IAS/IFRS as generally and consistently applied.

ARTICLE XV REPRESENTATIONS AND WARRANTIES

15.1 Due Organization, Valid Existence and Due Authorization. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article 4 hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Company additionally represents and warrants to Regeneron that it has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Regeneron Representations and Warranties. Regeneron additionally represents and warrants to Company that, as of the Effective Date:

(a) Regeneron has the right and authority to grant the rights and licenses granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that remain in effect which conflict with the rights and licenses granted herein;

(b) Except as set forth in Schedule 6, Regeneron is the sole owner of the Regeneron Patent Rights existing at the Effective Date, to Regeneron's knowledge, its title is free and clear of all liens, security interests and other encumbrances

(other than unilateral creditor filings, as to which this representation and warranty is made only to Regeneron's knowledge), and, except for the joint owner identified in Schedule 6 (and with respect to the Existing Licenses, the Third Party licensors referred to in Schedule 4), no Third Party has any right, title or interest in the Territory in the Field with respect to the Regeneron Patent Rights existing at the Effective Date;

(c) It has no knowledge that the making, using or selling of the VEGF Trap in the Field in the Territory would infringe any valid claims of the Patents of any Third Party in the Territory, nor does it have knowledge that any Third Party is infringing or misappropriating any of the Regeneron Intellectual Property;

(d) There are no judgments or settlements against or owed by Regeneron with respect to the Regeneron Intellectual Property owned by Regeneron;

(e) There are no claims, announced investigations, actions or other proceedings pending before or, to Regeneron's knowledge, threatened by any Regulatory Authority or other government agency with respect to the VEGF Trap, any Regeneron facility or, to Regeneron's knowledge, any other facility where the VEGF Trap is Manufactured, and Regeneron has not received written notice threatening any such claim, investigation, action or other proceeding;

(f) To the knowledge of Regeneron, the Development and Manufacture of VEGF Trap in the Field has been conducted by Regeneron and its Affiliates and its subcontractors in compliance in all material respects with applicable Laws, rules and regulations, and none of Regeneron or, to the knowledge of Regeneron, any of its Affiliates or subcontractors have received any notice in writing, or otherwise has knowledge of any facts, which have, or reasonably should have, led Regeneron to believe that any of the Registration Filings relating to the VEGF Trap in the Field are not currently in good standing with the FDA;

(g) To Regeneron's knowledge, neither Regeneron, nor any officer, employee or agent of Regeneron, has made an untrue statement of a material fact to any Regulatory Authority with respect to the VEGF Trap in the Field (whether in any submission to such Regulatory Authority or otherwise), or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the VEGF Trap in the Field;

(h) To Regeneron's knowledge, Regeneron and its employees, agents, clinical institutions and clinical investigators have materially complied with all FDA statutory and regulatory requirements with respect to VEGF Trap in the Field;

(i) Each Existing License is, to Regeneron's knowledge, in full force and effect as of the Effective Date. Regeneron has, to the extent contractually permitted, provided to Company, or allowed Company access to review, a true and complete copy of each Existing License. Regeneron will devote Commercially Reasonable Efforts to maintain the Existing Licenses in full force and effect and to perform its obligations thereunder and to keep Company informed of any material

development pertaining thereto that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement. Regeneron shall not, without the prior written approval of Company, (i) amend any provision of an Existing License that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement or (ii) make any election or exercise any right or option to terminate in whole or in part any Existing License to the extent such election or exercise would reasonably be expected to have a material adverse effect on Company's rights under this Agreement; and

(j) Regeneron has made available to Company, to the extent material, (i) written preclinical and clinical study results and protocols for the VEGF Trap in the Field, (ii) written communications to and from FDA with respect to the VEGF Trap in the Field, including but not limited to Registration Filings with the FDA and FDA minutes of meetings and telephone conferences, (iii) written FDA requests for data and studies with respect to the VEGF Trap in the Field and (iv) written reports of adverse drug experiences and other IND safety reports with respect to the VEGF Trap in the Field.

In reference to Section 15.3(c) above, the Parties acknowledge that they are aware of patents and pending patent applications owned by Genentech, Inc. that claim certain chimeric VEGF receptor compositions. Although Regeneron does not believe that the VEGF Trap infringes any valid claim in these patents or patent applications (if they were to issue), Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover the VEGF Trap. An adverse determination by a court in any such potential patent litigation would likely require the Parties to seek a license, which may not be available, or result in the Parties' inability to Develop, Manufacture or Commercialize the VEGF Trap in the Field in the Territory or in a damage award.

15.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) It will not during the Term grant any right or license to any Third Party in the Territory which would conflict with the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) Neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) In the course of the Development or Commercialization of a Licensed Product in the Field under this

Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE XVI CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Company and Regeneron acknowledges (subject to the further provisions of this Article 16 and the provisions of Article 19) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Company, Party Information provided to it under the confidentiality agreement between the Parties dated July 6, 2006) is confidential and proprietary to such other Party. Furthermore, each of Company and Regeneron acknowledges (subject to the further provisions of this Article 16) that all New Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article 16, each of Company and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Company and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents or any other Person under its authorization; provided such employees, agents or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided above, the restrictions provided in this Article 16 shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance

pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

(c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to the Regeneron Products (including the Manufacture or use thereof) (i) to Aventis or any other Third Party licensee or contractor of Regeneron engaged in, and for use in connection with, the development, manufacture and/or commercialization of Regeneron Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, (ii) in connection with Regeneron's Development, Manufacture and/or Commercialization of Regeneron Products outside the Field, (iii) to any Third Party licensee or contractor of Regeneron engaged in the Development, Manufacture and/or Commercialization of Regeneron Products in the Excluded Territory under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, and (iv) to Governmental Authorities or Regulatory Authorities as required by Law.

(d) Notwithstanding anything provided above or elsewhere in this Agreement, Company and its Affiliates shall have the right to use and disclose any New Information directly related to Company Products (including the Manufacture or use thereof) (i) to any Third Party licensee or contractor of Company or any of its Affiliates' engaged in and for use in connection with the development, manufacture and/or commercialization of Company Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, (ii) in connection with Company's or any of its Affiliates' Development, Manufacture, and/or Commercialization of Company Products outside the Field, (iii) to any Third Party licensee or contractor of Company engaged in the Development, Manufacture and/or Commercialization of Company Products in the Excluded Territory under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a

term of at least five (5) years and (iv) to Governmental Authorities or Regulatory Authorities as required by Law.

16.2 Injunctive Relief. Each Party acknowledges that damages resulting from breach of this Article 16 would not be an adequate remedy and that, notwithstanding the provisions of Article 10, in the event of any such disclosure or any indication of an intent to disclose such information, a Party owning such Party Information (or each Party with respect to New Information) shall be entitled to seek, by way of private litigation, injunctive relief or other equitable relief, in addition to any and all remedies available at law or in equity, including the recovery of damages and reasonable attorneys' fees, and in any such action for equitable relief in a court of competent jurisdiction, the Parties will not assert as a defense that there is an adequate remedy at law.

16.3 Publication of New Information. During the Term, if either Company or Regeneron (the "Publishing Party") desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).

16.4 Other Publications. The Parties will mutually agree upon the contents of a joint press release with respect to the execution of this Agreement which shall be issued simultaneously by both Parties on the Effective Date. During the Term, Company and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration (e.g., that the Collaboration is ongoing in accordance with the terms of this Agreement). Except as required by a Governmental Authority or applicable Law (including the rules and

regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 16 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Company acknowledges that Regeneron as a publicly traded company is legally obligated to make timely disclosures of all material events relating to Licensed Products. 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 will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE XVII INDEMNITY

17.1 Indemnity and Insurance.

(a) Company will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("**Regeneron Indemnitees**") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "**Damages**"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Company, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or

(ii) material breach by Company of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Company, its Affiliates and their respective officers, directors, employees, Sublicensees and agents (“Company Indemnitees”) from and against all Damages arising from or occurring as a result of a Third Party’s claim, action, suit, judgment or settlement against a Company Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Company or any other Company Indemnitee; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

(c) Subject to the last sentence of Section 19.6, in the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(d) Company agrees to indemnify the Regeneron Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Company’s or its Affiliates’ or Sublicensees’ Commercialization of Licensed Products in the Field in the Territory, except that Regeneron shall indemnify Company under Section 17.1(b) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee. Regeneron agrees to indemnify the Company Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Regeneron’s or its Affiliates’ or Sublicensees’ commercialization of Regeneron Products in the Field in the Excluded Territory, except that Company shall indemnify Regeneron under Section 17.1(a) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Company or any other Company Indemnitee. Company agrees to indemnify the Regeneron Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Company’s or its Affiliates’ or Sublicensees’

commercialization of Company Products in the Field in the Excluded Territory, except that Regeneron shall indemnify Company under Section 17.1(b) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee. Damages from product liability or other Third Party claims arising from the Development of any Licensed Product in the Field under this Agreement for which neither Party is entitled to indemnification under this Section 17.1 shall be treated as Development Costs.

(e) Immediately upon First Commercial Sale in the Territory, during the Term and for a period of five (5) years after the expiration of this Agreement or the earlier termination thereof, each Party shall use Commercially Reasonable Efforts to obtain and/or maintain (either directly or as a named insured on a Third Party insurance policy or policies), at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts, respectively, which are reasonable and customary for comparable products in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party; provided that Regeneron shall not be required to obtain or maintain such insurance in an amount greater than [*****] per incident and in the aggregate. Such product liability insurance or self-insured arrangements shall insure against personal injury, physical injury or property damage arising out of, for Regeneron, Manufacture of Licensed Products (if applicable) and sale, distribution or marketing of Regeneron Products in the Excluded Territory, and for Company, the sale, distribution or marketing of Licensed Products in the Territory.

(f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Company Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article 8; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article 8.

17.2 Indemnity Procedure. The Party entitled to indemnification under this Article 17 (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 or claims asserted or threatened against the Indemnified Party which 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 indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, 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 (i) 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; and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon 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 unreasonably withheld 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 litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(c) The amount of any Damages for which indemnification is provided under this Article 17 will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.

(d) If an Indemnified Party receives an indemnification payment pursuant to this Article 17 and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article 17 and (ii) the amount necessary to fully

and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article 17.

**ARTICLE XVIII
FORCE MAJEURE**

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

**ARTICLE XIX
TERM AND TERMINATION**

19.1 Term/Expiration of Term.

(a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated as provided hereafter, shall end at such time as neither Party, nor either Party's Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent; provided, that if at any time during the Term Company loses the exclusive legal right to Commercialize Licensed Product in the Field in any Major Market Country, whether due to expiration of Regeneron Patent Rights or expiration of any statutory marketing exclusivity period for Licensed Product in such Major Market Country, the Parties shall meet to discuss and attempt to enter into an amendment to this Agreement for the purpose of simplifying the governance structure hereunder.

(b) Upon expiration of the Term, except as set forth in this Agreement, all licenses and rights with respect to Products shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause. Company may terminate this Agreement with respect to the entire Territory for all Licensed Products in the Field on [*****] prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2, this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set

forth above (the "Termination Notice Period") and the terms of Schedule 7 shall apply. Except as set forth in this Section 19.2, Section 19.8 (last paragraph), or Schedule 7, during the Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products in the Field in accordance with Plans. During the Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Company hereunder and in any event upon the expiration of the applicable Termination Notice Period, whether or not any such notice is given by Regeneron, (a) the licenses and rights granted to Company hereunder shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the applicable Termination Notice Period) and (b) Company will promptly take the actions required by Schedule 7 and Regeneron will reasonably cooperate with Company (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory. In addition, during the Termination Notice Period, [*****] and (ii) neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the non-breaching Party from the Collaboration, taken as a whole.

19.4 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, effective immediately, upon written notice to Company, if Section 20.16 of this Agreement shall have been breached. For the avoidance of doubt, Company will not be deemed to have breached Section 20.16, and Regeneron shall not have the right to terminate this Agreement, as a result of an inadvertent breach of Section 20.16 arising from (a) discussion with any Third Parties that are initiated by such Third Parties, are not publicly disclosed and do not result in any actions referred to in paragraphs (a) through (g) of Section 20.16 or (b) any informal discussions covering general corporate or other business matters the purpose of which is not to effectuate or lead to any of the actions referred to in paragraphs (a) through (g) of Section 20.16.

19.6 [*****].

19.7 Effect of Termination.

(a) Except as set forth in Section 19.7(b) below, upon termination of this Agreement prior to expiration of the Term (and during the applicable Termination Notice Period or 6-Month Notice Period), the provisions of Schedule 7 shall apply, and except to the extent required by Company to fulfill its obligations pursuant to Schedule 7, (i) all licenses and rights granted by Regeneron to Company hereunder shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Company to Regeneron hereunder with respect to Company Products shall automatically terminate, and revert to Company, and (iii) the licenses from Company and its Affiliates

to Regeneron referred to in Schedule 7 shall come into full force and effect. In addition, upon termination of this Agreement prior to expiration of the Term (and during the applicable Termination Notice Period or 6-Month Notice Period), the following paragraphs of Schedule 8 shall apply with respect to any Company Products: (i) paragraph 1 of Schedule 8, (ii) paragraph 3 of Schedule 8 and (iii) paragraph 4 of Schedule 8. If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, then Company shall pay to Regeneron, in addition to any other amount payable by Company to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to (i) fifty percent (50%) of the Development Costs incurred by Regeneron under the Global Development Plan but excluding the Aggregate Regeneron Payment Amount, and (ii) one hundred percent (100%) of the Development Costs incurred by Regeneron under the Territory Development Plan, during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

(b) Upon termination of this Agreement by Company pursuant to Section 19.3 or 19.4, the provisions of Schedule 8 shall apply with respect to any Company Product and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 8, (i) all licenses and rights granted by Company to Regeneron hereunder with respect to Company Products shall automatically terminate, and revert to Company, (ii) all licenses and rights granted by Regeneron to Company hereunder with respect to Regeneron Products shall automatically terminate and revert to Regeneron and (iii) the licenses from Regeneron and its Affiliates to Company referred to in Schedule 8 shall come into full force and effect for the Company Products. In addition, upon termination of this Agreement by Company pursuant to Section 19.3 or 19.4, the following paragraphs of Schedule 7 shall apply with respect to any Regeneron Products: (i) paragraph 1 of Schedule 7, (ii) paragraph 3 of Schedule 7 and (iii) paragraph 4 of Schedule 7.

(c) [*****].

19.8 Survival of Obligations. Except as otherwise provided in this Article 19, Schedule 7 or Schedule 8, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Company nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance Payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero;

(b) subject to the provisions of this Article 19, including Schedule 7 and Schedule 8 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article 16, as well as other provisions (including, without limitation, Sections 6.16, 7.5, 9.7, 9.8, 9.10 and 10.3, and Articles 12 (with respect to Joint Inventions), 16, 17, 19 and 20) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and

(c) such expiration or termination and this Article 19 shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

Notwithstanding the foregoing or any other term or provision of this Agreement, (i) if Company terminates this Agreement under Section 19.2 or Section 19.6 and, during the Termination Notice Period or 6-Month Notice Period, as the case may be, Regeneron enters into a license agreement for a Licensed Product in the Field in the Territory substantially similar in scope as, and providing for the assumption and performance by the counterparty thereto of the obligations of Company under, this Agreement, Company's continuing obligations under the Plans pursuant to Section 19.2 or Section 19.6, as applicable, shall expire, and (ii) upon termination of this Agreement for any reason other than a material breach by Regeneron and consequent termination by Company under Section 19.3, except as set forth in Section 19.7(c), Regeneron's obligations with respect to Global Development Balance Payments to Company provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero.

ARTICLE XX MISCELLANEOUS

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to conflict of laws principles. Except as set forth in Article 10, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

20.2 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.

20.3 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 Schedule 9 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 facsimile transmission, 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 facsimile (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.

20.4 Entire Agreement. This Agreement contains the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Company and Regeneron.

20.6 Headings. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

20.7 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.

20.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either

Company or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Company or (b) the prior written consent of Company in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 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, and shall also inure to the benefit of the Regeneron Indemnitees and Company Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Without limiting the foregoing, each Party shall take reasonable efforts to ensure that each of its Affiliates engaged in the development or commercialization of ophthalmic products or technologies and which have know-how or technologies that are materially useful for the Development or Commercialization of Licensed Products, engage in the Development or Commercialization of Licensed Products or otherwise license their Know-How under this Agreement. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product or will otherwise license its Know-How under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate.

20.12 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.

20.13 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. No Third Party 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. Notwithstanding the

foregoing, Article 17 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Company Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Company nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Company, and Company's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR COMPANY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, 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 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS .

20.16 Standstill Agreement. During the period commencing on the Effective Date and expiring on the date which is five (5) years after the end of the Term, neither Company nor any of its Affiliates (for purposes of this Section 20.16, Company, together with such Affiliates, being referred to as the "Investor") shall:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock or any securities convertible into or exchangeable for Shares of Then Outstanding Capital Stock, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock, if after giving effect to such acquisition (and assuming the conversion of all convertible securities), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended) twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted

in Investor's ownership totaling twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock;

(b) directly or indirectly, propose or nominate for election to the Board of Directors of Regeneron any Person whose nomination has not been approved by a majority of the Board of Directors of Regeneron, or vote or cause to be voted in favor of such Person for election to the Board of Directors of Regeneron any Shares of Then Outstanding Capital Stock;

(c) directly or indirectly, accept or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of Regeneron (an "Acquisition Proposal");

(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 Securities Exchange Act) in opposition to the recommendation of a majority of the Board of Directors of Regeneron with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Capital Stock of Regeneron or any of its Affiliates;

(e) deposit any Shares of Then Outstanding Capital Stock in a voting trust or subject any Shares of Then Outstanding Capital Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Capital Stock;

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above;

(g) request or propose that Regeneron or any of Regeneron's officers or its Board of Directors amend, waive, or consider the amendment or waiver of any provisions set forth in this Section 20.16; or

(h) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in clauses (a) through (g) above;

provided that the mere voting of any Shares of Then Outstanding Capital Stock held by the Company shall not constitute a violation of any of clauses (a) through (f) above.

20.17 Termination of Standstill. Provided Investor has not violated Section 20.16(d), (f) or (h) with respect to the Offeror referred to in this Section 20.17, the restrictions contained in Section 20.16 shall terminate upon the earlier to occur of (a) the public announcement by an Offeror of an Acquisition Proposal; (b) the acquisition by an Offeror (other than Dr. Leonard Schleifer or his Affiliates) of beneficial ownership of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by the Offeror, represents more than [*****] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock; (c) the issuance by Regeneron to a Third Party

(other than an underwriter in a public offering which promptly distributes such shares to the public) of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by such Third Party, represents more than [*****] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock, if Regeneron does not enter into a standstill agreement with such Third Party for a time period and upon terms substantially similar to the provisions of Section 20.16; (d) a sale of all or substantially all of the assets of Regeneron (other than to a wholly owned subsidiary of Regeneron); or (e) a liquidation or dissolution of Regeneron, which would give rise to a termination of this Agreement pursuant to Section 19.4; provided, however, that if any of the transactions referred to in (a), (b) or (d) above terminates and Regeneron has not made a public announcement of its intent to solicit or engage in a transaction referred to in Section 20.16 (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of Regeneron, then the restrictions contained in Section 20.16 shall again be applicable.

20.18 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.19 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

IN WITNESS WHEREOF, Company and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

BAYER HEALTHCARE LLC

By /s/ Jeffrey M. Greenman
Name: Jeffrey M. Greenman
Title: General Counsel and Secretary

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration
and Chief Financial Officer

SCHEDULE 1

Manufacturing Cost

“Manufacturing Cost” as used in this Agreement shall be determined as provided in this Schedule 1.

A. General Principles

1. Regeneron shall supply Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements at Fully Burdened Manufacturing Cost, calculated as described in Section B below.

2. To the extent that a Manufacturing Plan includes the use of Formulated Bulk Product or Finished Product that was Manufactured by Regeneron prior to the Effective Date, Regeneron shall supply such Formulated Bulk Product or Finished Product at its actual average Fully Burdened Manufacturing Cost, calculated as described in Section B below, plus Cost of Finishing, as described in Section C below.

3. [*****]

4. If a Manufacturing Plan calls for Regeneron to reserve its facility to Manufacture Formulated Bulk Product, including, without limitation, purifying/processing the bulk drug substance, and the Parties subsequently amend the Manufacturing Plan such that the facility is not used as originally set forth therein, then Regeneron shall be reimbursed for what otherwise would have been its Fully Burdened Manufacturing Cost as if such facility had been used for Manufacturing as originally required in the Manufacturing Plan, except for such variable costs as are actually avoided or mitigated; provided, however, that Regeneron shall not be reimbursed hereunder if such amendment of the Manufacturing Plan has been agreed upon at least twelve (12) months prior to its effective date.

[*****]

SCHEDULE 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the “Quarterly True-Up”) equal to (a) the Territory Profit Split for such Quarter (as set forth in Part I), plus (b) the Regeneron Reimbursement Amount for such Quarter (as set forth in Part II), plus or minus (c) the Global True-Up (as set forth in Part III), minus (d) the Global Development Balance Payment (commencing in the Quarter of the First Commercial Sale in a Major Market Country) (as set forth in Part IV). In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Company to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Company in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. TERRITORY PROFIT SPLIT

The “Territory Profit Split” shall mean fifty percent (50%) of Territory Profits in a Quarter. “Territory Profits” shall mean aggregate Net Sales in the Territory in the Quarter less the sum of aggregate COGS and aggregate Shared Promotion Expenses incurred by both Parties in the Territory in the Quarter.

An example of a calculation of the Territory Profit Split in a Quarter would be:

	Aggregate	Company	Regeneron	Territory Profit Split
Net Sales in the Territory	1000	1000		
COGS	(50)	(50)	0	
Shared Promotion Expenses	(350)	(300)	(50)	
Territory Profits	600			300

II. REGENERON REIMBURSEMENT AMOUNT

The “Regeneron Reimbursement Amount” for a Quarter shall mean (a) Shared Promotion Expenses incurred by Regeneron in the Quarter (if any), plus (b) Commercial Supply Costs incurred by Regeneron in the Quarter (if any), plus (c) Development Costs incurred by Regeneron under the Territory Development Plan in the Quarter (if any).

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Promotion Expenses	50
Regeneron Commercial Supply Costs	10
Regeneron Development Costs under Territory Development Plan	5
Regeneron Reimbursement Amount	65

III. GLOBAL TRUE-UP

The “Global True-Up” for a Quarter shall mean (a) fifty percent (50%) of the sum of (i) aggregate Development Costs incurred by both Parties under the Global Development Plan in the Quarter and (ii) aggregate Other Shared Expenses incurred by both Parties in the Quarter, minus (b) one hundred percent (100%) of the sum of (i) Development Costs incurred by Company under the Global Development Plan in the Quarter and (ii) Other Shared Expenses incurred by Company during the Quarter. If the Global True-Up is a positive number, it shall be added in the calculation of the Quarterly True-Up and, if it is a negative number, the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.

An example of a calculation of the Global True-Up in a Quarter would be:

	Aggregate	Company	Regeneron	Global True-Up
Development Costs under Global Development Plan	80	30	50	
Other Shared Expenses	40	35	5	
Total	120	65	55	(5)

IV. GLOBAL DEVELOPMENT BALANCE PAYMENT

The “Global Development Balance” for a Quarter shall mean (a) twenty-five percent (25%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plan from January 1, 2007 through the close of such Quarter [*****] plus (b) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Territory Development Plan from the Effective Date through the close of such Quarter [*****] less (c) the aggregate amount of Global Development Balance Payments included in the calculation of the Quarterly True-Up in all prior Quarters.

The “Global Development Balance Payment” shall mean, [*****]

An example of a calculation of the Global Development Balance Payment in a Quarter would be:

Territory Profit Split	300
Global Development Balance	200
[*****]	[***]
Global Development Balance Payment	[***]

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-up in a Quarter would be:

Territory Profit Split	300
Regeneron Reimbursement Amount	65
Global True-Up	(5)
Global Development Balance Payment	[****]
Quarterly True-up	[**]

In this example, Company would pay Regeneron [***] in accordance with the terms set forth in Article 9.

A more detailed illustration of the calculations under this Schedule 2 will be prepared by the JFC promptly after the Effective Date.

SCHEDULE 3

Milestone Payments

I. DEVELOPMENT MILESTONES

The following non-refundable, non-creditable milestone payments shall be payable by Company to Regeneron upon the achievement of each applicable milestone event set forth below for each Regeneron Product in each Major Indication (but in no event more than two (2) Major Indications per Milestone Event). The term "Major Indication" shall include (i) the neovascular form of age-related macular degeneration, (ii) diabetic macular edema, [*****]. If an indication in the Field that is not initially considered by the Parties to be a Major Indication later is determined to be a Major Indication, then within thirty (30) days of such determination, Company shall pay to Regeneron any milestone payments for previous Milestone Events (as set forth below) that occurred with respect to the Development of any Regeneron Product(s) in such indication in the Territory.

Milestone	Payment	Milestone Event
1.	US \$20,000,000	For each Regeneron Product, upon administration of the Regeneron Product to the first patient in the first Phase 3 Trial for any Major Indication identified in a Development Plan
2.	[*****]	[*****]
3.	[*****]	[*****]
4.	[*****]	[*****]

For clarity and by way of example only, [*****]

II. SALES MILESTONES

In addition to all other amounts payable under this Agreement, Company shall make the following additional non-refundable, non-creditable milestone payments to Regeneron based on the aggregate Net Sales in any twelve (12) consecutive month time period ("Twelve Month Period"):

Milestone	Payment	Milestone Event
1.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed US \$200,000,000
2.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]

Milestone	Payment	Milestone Event
3.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]
4.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]
5.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]
6.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]
7.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]
8.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]
9.	[*****]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*****]

For clarity, “aggregate Net Sales” means the total of Net Sales of all Licensed Products in the Field in the Territory. For further clarity, one or more of the milestone payments set forth in this Section II of Schedule 3 may become payable based on the same milestone event. For example, [*****].

For purposes of further clarification, each separate milestone in this Section II of Schedule 3 may be achieved only once and the milestone numbers are included for reference purposes only.

For purposes of this Schedule 3, Net Sales will be converted to United States Dollars using the currency conversion procedure described in Section 9.6.

SCHEDULE 4

Existing Licenses

[*****]

SCHEDULE 5

Initial Development Plan

[*****]

SCHEDULE 6

Regeneron Patent Rights

[*****]

SCHEDULE 7

Termination Arrangements

1. Company shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information of Regeneron and its Affiliates, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any New Information and Party Information of Regeneron and its Affiliates. In addition, at Regeneron's request, Company shall collect and transfer to Regeneron any remaining inventory of Regeneron Product Promotional Materials, Regeneron Product sales training materials, Regeneron Product samples, and Regeneron Product inventory. Notwithstanding the foregoing, Company may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Excluded Territory Intellectual Property existing at the effective date of termination to Develop, Manufacture and Commercialize Regeneron Products in the Field.

3. Company shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Regeneron Products in the Field. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Company shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Company or its Affiliates or any of its Sublicensees to the extent specifically relating to Regeneron Products.

(b) Company shall assign and transfer to Regeneron (or its nominee) Company's entire right, title and interest in and to all Product Trademarks and Promotional Materials relating to Regeneron Products; provided that nothing herein is intended to convey any rights in or to Company's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Company shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Regeneron Products in the Field in the Territory) of all information (including any New Information) in its possession or

under its control to the extent directly relating to any Regeneron Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Company, or such other format as may be reasonably requested by Regeneron.

(d) Company shall use Commercially Reasonable Efforts to assign to Regeneron any applicable sublicenses to the extent related to any Regeneron Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to Development, Manufacture or Commercialization of any Regeneron Product in the Field in the Territory, as reasonably requested by Regeneron and subject to the German Employee Invention Act.

(e) Without limitation of Company's other obligations under this Schedule 7, to the extent Company or its Affiliate is Manufacturing (in whole or in part) Regeneron Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Company (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of Regeneron Products, and Regeneron shall purchase such Regeneron Products, at the same price, and on such other terms and conditions on which Company was supplying, or in the absence of termination would have been required to supply, such Regeneron Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Company that Regeneron is able to Manufacture or have Manufactured Regeneron Products on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture, and Commercialization of the Regeneron Products in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Regeneron shall not be required to provide Company any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 7; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Company may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

SCHEDULE 8

Termination Arrangements

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Company or, at Company's request, destroy, all documents containing New Information or Party Information of Company and its Affiliates, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any New Information related to the Development, Manufacture and Commercialization of Company Products and any Party Information of Company and its Affiliates. In addition, at Company's request, Regeneron shall collect and transfer to Company any remaining inventory of Company Product Promotional Materials, Company Product sales training materials, Company Product samples and Company Product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Company and its Affiliates shall have a worldwide, fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Regeneron Excluded Territory Intellectual Property existing at the effective date of termination to Develop, Manufacture and Commercialize Company Products in the Field.

3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Company to enable Company (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Company Products in the Field. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Regeneron shall transfer and assign to Company (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to Company Products.

(b) Regeneron shall assign and transfer to Company (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for Company Products and Promotional Materials relating to Company Products; provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Regeneron shall provide to Company (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Company Products) of all

information (including any New Information) in its possession or under its control to the extent directly relating to any Company Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Company.

(d) Regeneron shall use Commercially Reasonable Efforts to assign to Company any applicable sublicenses to the extent related to any Company Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to Development, Manufacture or Commercialization of any Company Product in the Field, as reasonably requested by Company, and subject to the German Employee Invention Act.

(e) Without limitation of Regeneron's other obligations under this Schedule 8, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) Company Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Company with Clinical Supply Requirements and/or Commercial Requirements of Company Products, and Company shall purchase such Company Products, at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Company Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Company notifies Regeneron that Company is able to Manufacture or have Manufactured Company Products on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Company Products in the Field hereunder to Company (or its Sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Company shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 8; provided, however, that Company shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Company of such licenses or other rights.

SCHEDULE 9

Notices

(a) If to Company:
Bayer HealthCare LLC
511 Benedict Avenue
Tarrytown, New York 10591
U.S.A.

With copy to:

Bayer HealthCare AG
51368 Leverkusen, Germany
Attention: General Counsel

And a copy to:

Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, Connecticut 06516
U.S.A.
Attention: General Counsel

(b) If to Regeneron:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President
Copy: General Counsel

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Nine months ended September 30, 2006
	2001	2002	2003	2004	2005	
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	\$(75,178)	\$(124,350)	\$(107,395)	\$ 41,565	\$(95,456)	\$ (72,179)
Fixed charges	3,888	13,685	14,108	14,060	13,687	10,232
Amortization of capitalized interest	—	—	33	78	78	58
Interest capitalized	—	(222)	(276)	—	—	—
Adjusted earnings	\$(71,290)	\$(110,887)	\$ (93,530)	\$ 55,703	\$(81,691)	\$ (61,889)
Fixed charges:						
Interest expense	\$ 2,657	\$ 11,859	\$ 11,932	\$ 12,175	\$ 12,046	\$ 9,033
Interest capitalized	—	222	276	—	—	—
Assumed interest component of rental charges	1,231	1,604	1,900	1,885	1,641	1,199
Total fixed charges	\$ 3,888	\$ 13,685	\$ 14,108	\$ 14,060	\$ 13,687	\$ 10,232
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the nine months ended September 30, 2006, the ratio coverage was less than 1:1. To achieve a coverage ration of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Nine months ended September 30, 2006
	2001	2002	2003	2005	
Coverage deficiency	\$75,178	\$124,572	\$107,638	\$95,378	\$72,121

**Certification of CEO 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 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: November 6, 2006

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

**Certification of CFO 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, Murray A. Goldberg, 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 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: November 6, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

**Certification of CEO and CFO 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 September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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.
Chief Executive Officer
November 6, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
November 6, 2006