## 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 (X) **EXCHANGE ACT OF 1934** 

For the quarterly period ended March 31, 2003

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)

777 Old Saw Mill River Road Tarrytown, New York

(Address of principal executive offices)

(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 X No

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of April 30, 2003:

Class of Common Stock

Number of Shares

Class A Stock, \$0.001 par value Common Stock, \$0.001 par value

2,408,548 44,497,128

10591-6707

13-3444607

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

(Zip Code)

## **TABLE OF CONTENTS**

PART I. FINANCIAL INFORMATION **ITEM 1. FINANCIAL STATEMENTS CONDENSED BALANCE SHEETS** CONDENSED STATEMENTS OF OPERATIONS CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY **CONDENSED STATEMENTS OF CASH FLOWS** Notes to Condensed Financial Statements Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Item 3. Quantitative and Qualitative Disclosure About Market Risk. Item 4. Controls and Procedures PART II. OTHER INFORMATION Item 1. Legal Proceedings Item 6. Exhibits and Reports on Form 8-K **SIGNATURE** Certifications COLLABORATION, LICENSE AND OPTION AGREEMENT STOCK PURCHASE AGREEMENT **REGISTRATION RIGHTS AGREEMENT CERTIFICATION OF CEO AND CFO** 

## REGENERON PHARMACEUTICALS, INC. Table of Contents March 31, 2003

Page Numbers

PART I	FINANCIAL INFORMATION	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at March 31, 2003 and December 31, 2002	3
	Condensed statements of operations (unaudited) for the three months ended March 31, 2003 and 2002	4
	Condensed statement of stockholders' equity (unaudited) for the three months ended March 31, 2003	5
	Condensed statements of cash flows (unaudited) for the three months ended March 31, 2003 and 2002	6
	Notes to condensed financial statements	7-14
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	15-28
Item 3	Quantitative & Qualitative Disclosure About Market Risk	28
Item 4	Controls and Procedures	28
PART II	OTHER INFORMATION	
Item 1	Legal Proceedings	29
Item 6	Exhibits and Reports on Form 8-K	29-30
SIGNATURE	PAGE	31
CERTIFICATIONS		32-35

## PART I. FINANCIAL INFORMATION

## **ITEM 1. FINANCIAL STATEMENTS**

#### REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT MARCH 31, 2003 AND DECEMBER 31, 2002 (Unaudited) (In thousands, except share data)

	March 31, 2003	December 31, 2002
ASSETS		
Current assets		
Cash and cash equivalents	\$ 191,586	\$ 80,077
Marketable securities	104,064	173,282
Restricted marketable securities	16,340	10,912
Accounts receivable	7,238	4,017
Prepaid expenses and other current assets	2,075	1,829
Inventory	8,437	6,831
Total current assets	329,740	276,948
Marketable securities	6,282	20,402
Restricted marketable securities	5,279	10,573
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	82,648	76,825
Other assets	6,492	6,826
Total assets	\$ 430,441	\$ 391,574
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 25,201	\$ 30,309
Deferred revenue, current portion	34,104	9,659
Capital lease obligations	61	150
Total current liabilities	59,366	40,118
Deferred revenue	5,460	5,475
Notes payable	200,000	200,000
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;		
2,486,181 shares issued and outstanding in 2003		
2,491,181 shares issued and outstanding in 2002	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; 44,421,013 shares issued and outstanding in 2003		
41,746,133 shares issued and outstanding in 2002	44	42
Additional paid-in capital	622,510	573,184
Unearned compensation	(3,051)	(3,643)
Accumulated deficit	(454,185)	(424,075)
Accumulated other comprehensive income	295	471
Total stockholders' equity	165,615	145,981
Total liabilities and stockholders' equity	\$ 430,441	\$ 391,574

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

## **REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)** *(In thousands, except per share data)*

	Three months ended	l March 31, 2002
Revenues		
Contract research and development	\$ 9,424	\$ 2,690
Contract manufacturing	712	2,251
	10,136	4,941
Expenses		
Research and development	34,390	25,477
Contract manufacturing	666	1,259
General and administrative	3,459	3,400
	38,515	30,136
Loss from operations	(28,379)	(25,195)
Other income (expense)		
Investment income	1,208	2,772
Interest expense	(2,939)	(3,022)
	(1,731)	(250)
Net loss	(\$ 30,110)	(\$ 25,445)
Net loss per share amounts, basic and diluted	(\$ 0.68)	(\$ 0.58)

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

## REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the three months ended March 31, 2003

(In thousands)

	Class A Stock		Class A Stock Common Stock		Additional	
	Shares	Amount	Shares	Amount	Paid-in Capital	Unearned Compensation
Balance, December 31, 2002	2,491	\$ 2	41,746	\$42	\$573,184	(\$3,643)
Issuance of Common Stock in connection with exercise of stock options			227		586	
Issuance of Common Stock to Novartis Pharma AG			2,400	2	47,998	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan					(5)	5
Issuance of Common Stock in connection with Company 401(k)						
Savings Plan contribution			43		747	
Conversion of Class A Stock to Common Stock	(5)		5			
Amortization of unearned compensation						587
Net loss						
Change in net unrealized gain on marketable securities						
Balance, March 31, 2003	2,486	\$ 2	44,421	\$44	\$622,510	(\$3,051)

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Loss
Balance, December 31, 2002	(\$424,075)	\$ 471	\$145,981	
Issuance of Common Stock in connection with exercise of stock options			586	
Issuance of Common Stock to Novartis Pharma AG			48,000	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			747	
Conversion of Class A Stock to Common Stock				
Amortization of unearned compensation			587	
Net loss	(30,110)		(30,110)	(\$30,110)
Change in net unrealized gain on marketable securities		(176)	(176)	(176)
Balance, March 31, 2003	(\$454,185)	\$ 295	\$165,615	(\$30,286)

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

## **REGENERON PHARMACEUTICALS, INC.** CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (L

In	thousands)	
	·····,	

	Three months ended March 31, 2003 2002	
Cash flows from operating activities		
Net loss	(\$ 30,110)	(\$ 25,445)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	2,288	2,008
Non-cash compensation expense	587	439
Changes in assets and liabilities		
(Increase) decrease in accounts receivable	(3,221)	236
Decrease (increase) in prepaid expenses and other assets	1,032	(3,148)
Increase in inventory	(1,324)	(735)
Increase (decrease) in deferred revenue	24,430	(1,788)
Increase in accounts payable, accrued expenses, and other liabilities	7,511	2,379
Total adjustments	31,303	(609)
Net cash provided by (used in) operating activities	1,193	(26,054)
Cash flows from investing activities Purchases of marketable securities	(5,566)	(127,745)
Purchases of restricted marketable securities	(5,500)	(127,710)
Sales of marketable securities	87,389	44,818
Maturities of restricted marketable securities	5,500	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Capital expenditures	(20,004)	(4,000)
Net cash provided by (used in) investing activities	61,819	(86,927)
Cash flows from financing activities		
Net proceeds from the issuance of stock	48,586	1,168
Capital lease payments	(89)	(111)
Net cash provided by financing activities	48,497	1,057
Net increase (decrease) in cash and cash equivalents	111,509	(111,924)
Cash and cash equivalents at beginning of period	80,077	247,393
Cash and cash equivalents at end of period	\$191,586	\$ 135,469

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

#### 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 generally accepted accounting principles. 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, 2002 Condensed Balance Sheet data was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles. 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, 2002.

Certain reclassifications have been made to the financial statements for the three months ended March 31, 2002 to conform with the current period's presentation.

## 2. Stock-based Employee Compensation

The accompanying financial position and results of operations of the Company have been prepared in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees.

The following table illustrates the effect on the Company's net loss and net loss per share had compensation costs for the Company's stock-based incentive plans been determined in accordance with the fair value based method of accounting for stock-based compensation as prescribed by Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation.



## **REGENERON PHARMACEUTICALS, INC.** Notes to Condensed Financial Statements

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

	Three months ended March 31,	
	2003	2002
Net loss, as reported	(\$ 30,110)	(\$ 25,445)
Add: Stock-based employee compensation expense included in reported net loss	587	439
Deduct: Total stock-based employee compensation expense determined		
under fair value based method for all awards	(11,585)	(11,333)
Pro forma net loss	(\$ 41,108)	(\$ 36,339)
Net loss per share amounts, basic and diluted:		
As reported	(\$ 0.68)	(\$ 0.58)
Pro forma	(\$ 0.93)	(\$ 0.83)

For the purpose of the pro forma calculation, the fair value of each option granted from the Company's stock-based incentive plans during the three months ended March 31, 2003 and 2002 was estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average fair value of the options granted during the three months ended March 31, 2003 and 2002 was \$14.36 and \$18.33, respectively. The following table summarizes the assumptions used in computing the fair value of option grants.

	Three months er	nded March 31,
	2003	2002
Expected volatility	80%	70%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.12%-4.01%	3.98%-4.72%

Under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan, the Company awards shares of Restricted Stock. Restrictions on these shares generally lapse with respect to 25% of the shares every six months over approximately a two-year period. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to these awards. The amount is based on the fair market value of shares of the Company's Common Stock on the grant date of the Restricted Stock award and is expensed, on a pro rata basis, over the period that the restrictions lapse. For the three months ended March 31, 2003 and 2002, the Company recognized compensation expense related to Restricted Stock awards of \$587 and \$439, respectively.

#### 3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2003 and December 31, 2002 are \$1,702 and \$13,490, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2002 and December 31, 2001 are \$2,569 and \$1,946, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2002 and 2001 are \$747 and \$764, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2003 and 2002, the Company contributed 42,543 and 21,953 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2003 and December 31, 2002 are \$674 and \$2,013, respectively, of accrued interest income. Included in marketable securities at March 31, 2002 and December 31, 2001 are \$2,652 and \$1,988, respectively, of accrued interest income.

#### 4. Inventories

Inventories consist of raw materials and other direct and indirect costs associated with production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement.

Inventories as of March 31, 2003 and December 31, 2002 consist of the following:

	March 31, 2003	December 31, 2002
Raw materials	\$ 403	\$ 357
Work-in-process	1,077	261(2)
Finished products	6,957(1)	6,213(3)
	\$8,437	\$6,831

<sup>(1)</sup> Net of reserves of \$1,921.

- $^{(2)}$  Net of reserves of \$32.
- <sup>(3)</sup> Net of reserves of \$1,223.

## 5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2003 and December 31, 2002 consist of the following:

	March 31, 2003	December 31, 2002
Accounts payable	\$ 9,515	\$13,297
Accrued payroll and related costs	4,016	4,162
Accrued clinical trial expense	4,567	4,515
Accrued capital expenditures	122	4,322
Accrued expenses, other	1,939	1,721
Interest payable on convertible notes	5,042	2,292
	\$25,201	\$30,309

## 6. 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 or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended March 31, 2003 and 2002, the components of comprehensive loss are:

	Three Months Ended		
	March 31,		
	2003	2002	
Net loss	(\$30,110)	(\$25,445)	
Change in net unrealized gain on marketable securities	(176)	(797)	
Total comprehensive loss	(\$30,286)	(\$26,242)	
		, , ,	

## 7. Collaboration and License Agreement

In March 2003, the Company entered into a collaboration agreement (the "Novartis Agreement") with Novartis Pharma AG ("Novartis") to jointly develop and commercialize the Interleukin-1 Cytokine Trap ("IL-1 Trap"). In connection with this agreement, Novartis made a non-refundable up-front payment of \$27.0 million and purchased \$48.0 million of newly issued unregistered shares of the Company's Common Stock. Initially, Regeneron issued 2,400,000 shares of Common Stock to Novartis; however, the final number of shares issued to Novartis totaled 7,527,050 based upon the average closing price of the Common Stock for the 20 consecutive trading days ending May 12, 2003.



Development expenses incurred during 2003 will be shared equally by the Company and Novartis. Regeneron may fund its share of 2003 development expenses through a loan (the "2003 Loan") from Novartis, which will bear interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly. The 2003 Loan and accrued interest thereon will be forgiven should certain defined pre-clinical and clinical milestones be reached; otherwise, such amounts are payable on July 1, 2004. As of March 31, 2003, the Company has not drawn on the 2003 Loan facility.

Development expenses incurred subsequent to 2003 will be shared by the Company and Novartis, as set forth in the Novartis Agreement, with funding for Regeneron's share of these expenses available through another loan (the "Post-2003 Loan") from Novartis. Also, Regeneron's share of promotional expenses prior to product launch, as defined, may be funded through an additional loan (the "Promotion Expense Loan") from Novartis. These loans will bear interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly. The Post-2003 Loan and the Promotion Expense Loan, including accrued interest thereon, will be due five and three years, respectively, after the earlier of either the first commercial sale of an IL-1 Trap product in the United States or Europe or the effective date of termination of the agreement by Novartis.

Novartis has the right to terminate the agreement without cause with at least nine months advance notice.

The Company and Novartis will share co-promotion rights and profits on sales, if any, of the IL-1 Trap. In addition, the Company may receive up to \$275.0 million in milestone payments upon the receipt of specified regulatory approvals and the achievement of certain product revenues targets. Also, under the Novartis Agreement, the Company and Novartis each has the option to collaborate on the development and commercialization of additional defined IL-1 product candidates that Regeneron and Novartis are currently developing independently.

Revenue related to payments from Novartis, including the up-front payment of \$27.0 million, reimbursement of Novartis' share of Regeneron-incurred development expenses, forgiveness of any loans, and the initial milestone payment upon receipt of the first specified regulatory approval is being recognized on a percentage of completion basis in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*. Further regulatory and product revenues milestone payments will be recognized if and when earned. For the three months ended March 31, 2003, the Company recognized \$6.7 million of contract research and development revenue in connection with the Novartis Agreement. At March 31, 2003, amounts receivable from Novartis totaled \$4.5 million and deferred revenue was \$24.8 million.

#### 8. Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. For the three months ended March 31, 2003 and 2002, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

Three Months Ended March 31,	Net Loss, in thousands (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2003:			
Basic and diluted	(\$30,110)	44,309	(\$0.68)
2002:			
Basic and diluted	(\$25,445)	43,822	(\$0.58)

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

	Three Months F 2003	Ended March 31, 2002
Options:		
Weighted average number, in thousands	11,534	9,423
Weighted average exercise price	\$ 21.30	\$21.46
Restricted Stock:		
Weighted average number, in thousands	178	98
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$30.25

#### 9. Segment Reporting

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 potential therapeutics for human medical conditions, and the development and commercialization

#### **REGENERON PHARMACEUTICALS, INC.** Notes to Condensed Financial Statements

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

of these discoveries. Also includes revenues and expenses related to the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements.

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

The table below presents information about reported segments for the three months ended March 31, 2003 and 2002:

	Three Months Ended March 31, 2003			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 9,424	\$ 712	—	\$ 10,136
Depreciation and amortization	2,027	(1)	\$ 261	2,288
Interest expense	2	—	2,937	2,939
Net (loss) income	(28,427)	46	$(1,729)^{(2)}$	(30,110)
Capital expenditures	8,132		—	8,132
Total assets	85,924	12,399	332,118(3)	430,441

	Three Months Ended March 31, 2002				
	Research & Development	Contract Manufacturing	Reconciling Items	Total	
Revenues	\$ 2,690	\$ 2,251	—	\$ 4,941	
Depreciation and amortization	1,747	(1)	261	2,008	
Interest expense	11	—	3,011	3,022	
Net (loss) income	(26,198)	992	$(239)^{(2)}$	(25,445)	
Capital expenditures	4,602	21		4,623	
Total assets	39,642	10,129	422,094(3)	471,865	

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

(2) Represents investment income, net of interest expense related to convertible notes issued in October 2001.

(3) Includes cash and cash equivalents, marketable securities, restricted marketable securities, prepaid expenses and other current assets, and other assets.

## 10. Legal Matters

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of the Company's officers and directors in the United States District Court for the Southern District of New York. The complaints, which purport to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. The Company's management believes that the lawsuits are without merit. The ultimate outcome of these matters cannot presently be determined. Accordingly, no provision for any liability that may result upon the resolution of these matters has been made in the accompanying financial statements.

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

#### General

**Overview.** The discussion below contains forward-looking statements that involve risks and uncertainties relating to the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible therapeutic applications of our product candidates and research programs, the timing, nature, and success of the clinical and research programs now underway or planned, and the future 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 "Factors That May Affect Future Operating Results" 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.

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic products for the treatment of serious medical conditions. Our clinical and pre-clinical pipeline includes product candidates for the treatment of obesity, rheumatoid arthritis and other inflammatory conditions, cancer and related disorders, allergies, asthma, and other diseases and disorders. Developing and commercializing new medicines entails risk and significant 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 combine our strong foundation in basic scientific research and discovery-enabling technology 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 have the potential to address a variety of unmet medical needs. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms, which are designed to discover specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models in which a specific gene is removed (referred to as "knock-out") or is overproduced (referred to as "transgenic"). We will continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Below is a summary of our leading clinical and pre-clinical research programs. With the exception of the IL-1 Trap, which we are developing in collaboration with

#### **Table of Contents**

Novartis Pharma AG, we retain sole ownership and marketing rights for each of these programs and currently are developing them independently of any corporate partners.

AXOKINE®: Acts on the brain region regulating food intake and energy expenditure and is being developed for the treatment of obesity. In March 2003, we reported data from the 12-month treatment period of our initial Phase III pivotal trial of AXOKINE. This trial enrolled approximately 2000 patients and involved a 12-month treatment period in which subjects received daily subcutaneous self-injections of placebo or AXOKINE. The study demonstrated that subjects receiving AXOKINE experienced a greater average weight loss than those receiving placebo (6.2 lbs. vs. 2.6 lbs, p<.001) and that a greater proportion of AXOKINE-treated subjects lost at least 5 percent of their initial body weight compared with placebo-treated subjects (25.1 percent vs. 17.6 percent, p<.001). The study also showed that AXOKINE had a favorable safety and tolerability profile. The treatment period in this study is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE.

Although the results of the Phase III study were statistically significant, the average weight loss for the entire treatment group was small. AXOKINEassociated weight loss was limited by the development of antibodies in approximately two-thirds of the AXOKINE-treated subjects beginning after about three months of treatment. In the patients who did not become resistant to AXOKINE treatment through the development of antibodies, the weight loss appeared in line with currently available treatments for obesity.

In April 2003, we announced the results of a 12-week Phase II clinical trial to assess the safety and efficacy of AXOKINE in overweight and obese individuals with type 2 diabetes mellitus. The study showed that treatment with AXOKINE resulted in statistically significant and dose-dependent weight loss, which was in line with the Phase III pivotal trial at the same 12-week time point. This trial currently is in a 12-week open-label extension phase.

We intend to discuss the data from the completed AXOKINE trials with the U.S. Food and Drug Administration before determining the future development plan for AXOKINE.

We are also evaluating a pegylated version of AXOKINE, which is in pre-clinical development. We are working to develop a suitable formulation of pegylated AXOKINE.

**INTERLEUKIN-1 CYTOKINE TRAP (IL-1 Trap):** Protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. IL-1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In July 2002, we announced the initiation of a dose-ranging Phase II trial that will involve approximately 200 participants to study the safety and efficacy of the IL-1 Trap in

people with rheumatoid arthritis. This trial was fully enrolled in the first quarter of 2003. Subjects in the study are receiving, in a double-blind manner, either placebo or one of three different dose levels of the IL-1 Trap. The results from this trial are expected to be available mid-year 2003. In March 2003, we entered into an agreement with Novartis to jointly develop and commercialize the IL-1 Trap throughout the world, with the exception of Japan, where product rights remain with Regeneron.

- VEGF TRAP: Protein-based therapeutic candidate designed to bind Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF) and prevent its interaction with cell surface receptors. VEGF is required for the growth of blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leak. In 2001, we initiated a dose-escalation Phase I clinical trial designed to assess the safety and tolerability of the VEGF Trap in subjects with solid tumor malignancies and/or non-Hodgkin's lymphoma. This trial continues to test increasing doses of the product candidate as per the protocol and is expected to end in the first half of 2004. Additional studies of the VEGF Trap in cancer are being planned. We are also evaluating the VEGF Trap in preclinical studies as a potential treatment for diseases of the eye.
- INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/13 Trap): Protein-based product candidate designed to bind the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines and prevent their interaction with cell surface receptors. IL-4 and IL-13 are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. In October 2002, we initiated a Phase I trial for the IL-4/13 Trap in adult subjects with mild to moderate asthma. This placebo-controlled, double-blind, dose escalation study is designed to assess the safety and tolerability of the IL-4/13 Trap. The trial is expected to end in the second half of 2003. We are continuing our research on IL-4 and IL-13 in other inflammatory conditions beyond asthma, which may lead to new potential indications for the IL-4/13 Trap.
- ANGIOPOIETINS: A new family of growth factors that act specifically on the endothelium cells that line blood vessels. Angiopoietins may be useful for growing blood vessels in diseased hearts and other tissues with decreased blood flow and for repairing blood vessel leaks that cause swelling and edema in many different diseases such as stroke, diabetic retinopathy, and inflammatory diseases. We have an active pre-clinical research program covering this family of growth factors. We have not yet selected a specific molecule to advance into clinical development or a specific indication for development.

In addition, we have formed collaborations to advance other research and development efforts. We are conducting research with The Procter & Gamble Company in muscle diseases and other fields. We are also collaborating with Medarex, Inc. to discover, develop, and commercialize certain human antibodies as therapeutics. In partnership with Amgen Inc., we have development rights to Neurotrophin-3, or NT-3, a clinical compound for the treatment of constipating conditions, although there are no

#### **Table of Contents**

ongoing development activities for NT-3 at this time. In all of these research collaborations, we retain 50% of the commercialization rights.

#### Discussion of First Quarter 2003 Activities

In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese subjects. The initial pivotal Phase III trial was a double-blind, randomized, placebo-controlled study that enrolled approximately 2,000 subjects at 65 sites across the United States. In March 2003, we reported data from the 12-month treatment period of the trial during which subjects received daily subcutaneous self-injections of placebo or AXOKINE at a dose of 1.0 microgram per kilogram of body weight (mcg/kg). The study demonstrated that subjects receiving AXOKINE experienced a greater average weight loss than those receiving placebo (6.2 pounds vs. 2.6 pounds, p<.001) and that a greater proportion of AXOKINE-treated subjects lost at least 5 percent of their initial body weight compared with placebo-treated subjects (25.1 percent vs. 17.6 percent, p<.001). AXOKINE also achieved statistically significant results in two of the three secondary endpoints, including the proportion of subjects losing at least 10% of their initial body weight. The study also showed that AXOKINE had a favorable safety and tolerability profile. The treatment period is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. As of March 31, 2003, the average treatment period for people in this trial was 17 months.

Although the results of the Phase III study were statistically significant, the average weight loss for the entire treatment group was small. AXOKINEassociated weight loss was limited by the development of antibodies in approximately two-thirds of the AXOKINE-treated subjects beginning after about three months of treatment. In the patients who did not become resistant to AXOKINE treatment through the development of antibodies, the weight loss appeared in line with currently available treatments for obesity. A more complete discussion of the results of this trial is contained in our Annual Report on Form 10-K for the year ended December 31, 2002.

In April 2003, we announced the results of a 12-week Phase II clinical trial to assess the safety and efficacy of AXOKINE in 157 overweight and obese individuals with type 2 diabetes mellitus who were treated with placebo or AXOKINE at doses of 1.0 mcg/kg and 0.5 mcg/kg per day. Subjects who were treated with AXOKINE at the 1.0 mcg/kg dose with dietary counseling lost 6.5 pounds on average, while those treated with placebo and dietary counseling lost only 2.5 pounds (p<.01). Trends toward improvements in blood glucose and other metabolic parameters were also observed during this small, short-term study. AXOKINE was generally well tolerated with no AXOKINE-related serious adverse events. Approximately 90 percent of study participants completed the 12-week study. This trial currently is in a 12-week open-label extension phase.

In this trial, approximately one-third of the subjects who were treated with the 1.0 mcg/kg dose of AXOKINE developed antibodies to AXOKINE at the 12-week time point. In the recently completed Phase III study of AXOKINE in non-diabetic subjects,

about half of AXOKINE-treated participants developed antibodies at the 12-week time point. This lower incidence of antibodies observed in the Phase II study will need to be explored in a larger Phase III study in the diabetic population. In the Phase III one-year study, further weight loss beyond 12 weeks appeared to be limited in those people who developed antibodies.

In addition, in July 2002, we completed enrollment for two trials, each of which includes approximately 300 subjects, which are evaluating the safety of intermittent treatment with AXOKINE and studying maintenance of weight loss following short-term treatment regimens. In January 2003, we announced that AXOKINE had received fast track designation from the FDA for the treatment of severely obese people who are unresponsive to, intolerant of, or unsuitable candidates for certain FDA-approved medicines for the long-term treatment of obesity.

We plan to discuss the data from the completed AXOKINE studies with the U.S. Food and Drug Administration before determining the future development plan for AXOKINE.

We are also evaluating a pegylated version of AXOKINE, which is in pre-clinical development. We are working to develop a suitable formulation of pegylated AXOKINE.

In July 2002, we announced the initiation of a dose-ranging Phase II study of the IL-1 Trap in subjects with rheumatoid arthritis. This trial enrolled approximately 200 subjects who will receive weekly self-injections of one of three fixed doses of IL-1 Trap or placebo for 12 weeks, followed by 10 weeks of open-label follow-up. The results from this trial are expected to be available mid-year 2003. The IL-1 Trap is also being evaluated for potential uses in treating other inflammatory diseases.

In March 2003, we entered into a Collaboration, License and Option Agreement with Novartis Pharma AG to jointly develop and commercialize the IL-1 Trap in rheumatoid arthritis and other indications throughout the world with the exception of Japan, where product rights remain with Regeneron. We and Novartis will share equally in all profits from future sales of the IL-1 Trap in North America and Europe. In other markets, Novartis will be entitled to receive 75 percent of the profits and we will be entitled to 25 percent of the profits. We may co-promote the IL-1 Trap in all territories under the agreement. As part of the agreement, Novartis purchased \$48.0 million of Regeneron's common stock and made a non-refundable up-front payment of \$27.0 million. The agreement is described in greater detail in the section of this report titled "Liquidity and Capital Resources".

Antagonists for IL-4 and IL-13 may be therapeutically useful in a number of allergy and asthma-related conditions, including as an adjunct to vaccines where blocking IL-4 and IL-13 may help to elicit more of the desired type of immune response to the vaccine. We have developed both an IL-4 Trap and an IL-4/13 Trap, which is a single molecule that can block both interleukin-4 and interleukin-13. In October 2002, we

initiated a Phase I clinical trial of a dual IL-4/13 Trap to assess the safety and tolerability of increasing dose levels in subjects with mild to moderate asthma. The Phase I trial is expected to end in the second half of 2003. We are continuing our research of IL-4 and IL-13 in other inflammatory conditions beyond asthma, which may lead to new potential indications for the IL-4/13 Trap.

In November 2001, we initiated a Phase I clinical trial designed to assess the safety and tolerability of VEGF Trap in patients with solid tumor malignancies and subjects with non-Hodgkin's lymphoma. The Phase I trial is an open-label study in subjects with advanced tumors and will evaluate the VEGF Trap in increasing dose levels. The study is being conducted at three clinical sites in the United States. Higher doses of VEGF Trap are expected to be studied as the trial progresses and we anticipate the study to end in the first half of 2004. Additional studies of the VEGF Trap in cancer are also being planned. We are also evaluating the VEGF Trap in preclinical studies as a potential treatment for diseases of the eye.

A minority of all research and development programs ultimately results in commercially successful pharmaceutical drugs; it is not possible to predict whether any program will succeed until it actually produces a medicine that is commercially marketed for a significant period of time. In addition, in each of the areas of our independent and collaborative activities, other companies and entities are actively pursuing competitive paths toward similar objectives. The results of Regeneron's and its collaborators' past activities in connection with the research and development of AXOKINE, Cytokine Traps, Angiopoietins, cancer, abnormal bone growth, muscle atrophy, small molecules, NT-3, and other programs or areas of research or development do not necessarily predict the results or success of current or future activities including, but not limited to, any additional preclinical or clinical studies. We cannot predict whether, when, or under what conditions any of our research or product candidates, including without limitation AXOKINE, IL-1 Trap, VEGF Trap, or IL-4/13 Trap will be shown to be safe or effective to treat any human condition or be approved for marketing by any regulatory agency. The delay or failure of current or future studies to demonstrate the safety or efficacy of its product candidates to treat human conditions or to be approved for marketing could have a material adverse impact on Regeneron. We discuss the risks associated with pharmaceutical drug development in the section of this report titled "Factors That May Affect Future Operating Results."

We have not received revenue from the commercialization 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 our research and development efforts and obtaining regulatory approval from the FDA or regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies noncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2003, we had a cumulative loss of \$454.2 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. Our activities may expand over time and may 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 timing of certain expenses and on the progress of our research and development efforts.

#### **Results of Operations**

*Three months ended March 31, 2003 and 2002.* Our total revenue increased to \$10.1 million for the first quarter of 2003 from \$4.9 million for the same period of 2002, contract research and development revenue increased to \$9.4 million for the first quarter of 2003 from \$2.7 million for the same period of 2002, as we recognized \$6.7 million of revenue related to our IL-1 Trap collaboration with Novartis. We recognize revenue in connection with the collaboration using the percentage of completion method in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*. In addition, we recognized \$2.6 million of contract research and development revenue from Procter & Gamble in both the first quarter of 2003 and 2002 in connection with our long-term collaboration agreement. Contract manufacturing revenue, related primarily to our long-term agreement with Merck & Co., Inc. to manufacture a vaccine intermediate at our Rensselaer, New York facility, decreased to \$0.7 million for the first quarter of 2003 from \$2.3 million for the same period of 2002, because product in inventory during the first quarter of 2003 will not be shipped to Merck until later this year. Contract manufacturing revenue and the related manufacturing expense are recognized as product is accepted and shipped.

Our total operating expenses increased to \$38.5 million for the first quarter of 2003 from \$30.1 million for the same period of 2002. Research and development expenses increased to \$34.4 million for the first quarter of 2003 from \$25.5 million for the comparable period of 2002, as activity in our clinical research programs increased, especially related to our Phase III clinical program for AXOKINE and our Phase II clinical study for the IL-1 Trap. Research and development expenses were 89% of total operating expenses in the first quarter of 2003, compared to 85% for the same period of 2002. Contract manufacturing expenses related to our long-term agreement with Merck decreased to \$0.7 million for the first quarter of 2003 from \$1.3 million for the same period of 2002, because product in inventory during the first quarter of 2003 will not be shipped to Merck until later this year. General and administrative expenses remained relatively unchanged at \$3.5 million for the first quarter of 2003 compared to \$3.4 million for the same period of 2002.

Investment income decreased to \$1.2 million for the first quarter of 2003 from \$2.8 million for the same period of 2002 due to lower effective interest rates on investment securities and lower levels of interest-bearing investments in the first quarter of 2003 as the Company funded its operations. Interest expense, incurred primarily on \$200.0 million of convertible notes issued in October 2001, declined slightly to \$2.9

million for the first quarter of 2003 from \$3.0 million for the same period of 2002. The notes, which mature in 2008, bear interest at 5.5% per annum.

Our net loss for the first quarter of 2003 was \$30.1 million, or \$0.68 per share (basic and diluted), compared to a net loss of \$25.4 million, or \$0.58 per share (basic and diluted), for the same period of 2002.

#### Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of equity securities, a private placement of convertible debt, revenue earned under our agreements with Amgen, Sumitomo Chemical Co., Ltd., Sumitomo Pharmaceuticals Company, Ltd., Merck & Co., Inc., Procter & Gamble, and Novartis, and investment income.

In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. Novartis made a nonrefundable up-front payment of \$27.0 million and purchased \$48.0 million of newly issued unregistered shares of our common stock. Initially, Regeneron issued 2,400,000 shares of common stock to Novartis; however, the final number of shares issued to Novartis totaled 7,527,050 based upon the average closing price of the common stock for the 20 consecutive trading days ending May 12, 2003.

Development expenses incurred during 2003 will be shared equally by Regeneron and Novartis. We may fund our share of 2003 expenses through a loan from Novartis that will be forgiven, together with accrued interest, should certain pre-clinical and clinical milestones be reached and is otherwise payable on July 1, 2004. As of March 31, 2003, we have not drawn on this loan facility. In addition, at March 31, 2003, \$4.5 million was receivable from Novartis for their share of IL-1 Trap development expenses incurred by Regeneron during the first quarter of 2003.

After 2003, Novartis will be responsible for any additional pre-Phase III development expenses, and the companies will share Phase III development expenses and pre-launch expenses. Our share of these expenses may be funded through two additional loans from Novartis. The loan and accrued interest for our share of Phase III development expenses is repayable in full five years after the initial product launch of the IL-1 Trap or five years after termination of Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. The loan and accrued interest for our share of pre-launch expenses is repayable in full five years after termination of Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. Novartis has the right to terminate the collaboration agreement without cause with at least nine months advance notice.

We and Novartis will share co-promotion rights and profit on sales, if any, of the IL-1 Trap. In addition, we may receive up to \$275.0 million in milestone payments upon receipt of specified regulatory approvals in the United States and the European Union and

the achievement of certain product revenues targets. Under the agreement, each company also has the right to elect to collaborate on the development and commercialization of certain other pre-clinical/early development IL-1 antagonists that we and Novartis currently are developing independently. Regeneron will continue to manufacture clinical supplies of the IL-1 Trap at our plant in Rensselaer, New York. Novartis will be responsible for providing commercial scale manufacturing capacity for the IL-1 Trap.

Under a long-term collaboration agreement, Procter & Gamble provides funding through December 2005 of \$2.5 million per quarter, plus adjustments for inflation, in support of our research efforts.

At March 31, 2003, we had \$323.6 million in cash, cash equivalents, marketable securities, and restricted marketable securities. We have no off-balance sheet financing arrangements and do not guarantee the obligations of any other entity. As of March 31, 2003, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. We may seek additional funding through, among other things, future collaboration agreements and public or private financing. We cannot assure you that additional financing will be available to us or, if available, that it will be available on acceptable terms.

Our additions to property, plant, and equipment totaled \$8.1 million and \$4.6 million for the first three months of 2003 and 2002, respectively.

We expect to incur substantial funding requirements for, among other things, research and development activities (including preclinical and clinical testing), expansion and validation of manufacturing facilities, and the acquisition of equipment. We currently anticipate that for the remainder of 2003, approximately 30-50% of our expenditures will be directed toward the pre-clinical and clinical development of product candidates, including AXOKINE, IL-1 Trap, IL-4/13 Trap, VEGF Trap, and the angiopoietins; approximately 5-15% of our expenditures will be invested in expansion of our manufacturing facilities; approximately 10-20% of our expenditures will cover our basic research activities; approximately 5-15% of our expenditures will be directed toward the continued development of our novel technology platforms, including potential efforts to commercialize these technologies; and the remainder of our expenditures will be for general corporate purposes, including working capital. For the remainder of 2003, we expect to incur approximately \$15 million in capital expenditures for our expanded manufacturing and research and development activities.

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.

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 drug candidates, and the continuation, extent, and success of any collaborative research arrangements (including those with Procter & Gamble, Novartis, Medarex, Emisphere Technologies, Inc., and Amgen). 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. We believe that our existing capital resources will enable us to meet operating needs through at least the end of 2004. However, this is a forward-looking statement based on our current operating plan, and we cannot assure you that there will be no 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. 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. 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.

#### Factors That May Affect Future Operating Results

We caution shareholders and potential investors that the following important factors, among others, in some cases have affected, and in the future could affect, our actual results and could cause our actual results to differ materially from those expressed in any forward-looking statements made by, or on behalf of, us. The statements under this caption are intended to serve as cautionary statements within the meaning of the Private Securities Litigation Reform Act of 1995. The following information is not intended to limit in any way the characterization of other statements or information under other captions as cautionary statements for such purpose:

• Delay, difficulty, or failure of a clinical trial of any of our product candidates, including clinical trials of our product candidates AXOKINE and the IL-1 Trap. If either or both of these product candidates fail to advance in the clinic, our business will be severely harmed and our stock price will be adversely affected. A clinical trial can fail or be delayed as a result of many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects, 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 also fail because it did not include a sufficient number of patients to detect the endpoint

being measured. For example, the pending trials studying the maintenance of weight loss following short-term treatment regimens with AXOKINE may be underpowered to detect statistically significant differences between patients treated with AXOKINE and those taking placebo following the post-treatment maintenance periods. These trials were designed before we had access to the data from the recently completed Phase III trial, which demonstrated that the magnitude of the average difference in weight loss observed between all AXOKINE-treated subjects and those taking placebo was small.

- In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our pharmaceutical 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 experiments and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date in some cases even after pivotal clinical trials have been successfully completed. Subjects who have received AXOKINE and the IL-1 Trap in clinical trials have developed antibodies.
- Delay, difficulty, or failure in obtaining regulatory approval for our products, including delays or difficulties in development because of insufficient proof of safety or efficacy or the failure to manufacture product candidates in accordance with FDA requirements.
- Delay, difficulty, or failure of our research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by us or others.
- Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, our agreements with Procter & Gamble and Novartis) and the resulting loss of research or other funding could have a material adverse effect on us and our operations.
- Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.
- Competitive or market factors that may cause use of our products to be limited or otherwise fail to achieve broad acceptance.
- The ability to obtain, maintain, and prosecute intellectual property rights and the cost of acquiring in-process technology and other necessary intellectual property rights, either by license, collaboration, or purchase of another entity.

#### **Table of Contents**

- Difficulties or high costs of obtaining adequate financing to fund the cost of developing and manufacturing product candidates.
- Amount and rate of growth of our general and administrative expenses, and the impact of unusual charges resulting from our ongoing evaluation of our business strategies and organizational structure.
- Failure of corporate partners to develop or commercialize successfully our products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between our corporate partners and us.
- Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology products in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.
- Difficulties in manufacturing sufficient amounts of our product candidates suitable for clinical testing or commercialization. Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations and manufacturing processes to support large scale clinical testing of our product candidates, including AXOKINE, IL-1, Trap, IL-4/13 Trap, VEGF Trap, and pegylated AXOKINE, 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 product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates. For example, AXOKINE currently is formulated for delivery in single use vials. We are in the process of developing a formulation that may be used in multiple use vials. If we are unable to develop this multiple use vial formulation, potential future AXOKINE sales and profitability may be limited.
- Difficulties in obtaining key raw materials and supplies for the manufacture of our product candidates.
- Failure of service providers upon whom we rely to carry out our clinical development programs, such as contract research organizations and third parties who fill and label our clinical supplies, to perform their contractual responsibilities. These failures could lead to delays in our clinical development programs.
- The costs and other effects of legal and administrative cases and proceedings (whether civil litigation, such as product liability, commercial, employment-related, or environmental claims, or criminal litigation), settlements, and

investigations; developments or assertions by or against us relating to intellectual property rights and licenses; the issuance and use of patents and proprietary technology by us and our competitors, including the possible negative effect on our ability to develop, manufacture, and sell our products in circumstances where we are unable to obtain licenses to patents which may be required for our products.

- Underutilization of our existing or new manufacturing facilities or of any facility expansions, resulting in inefficiencies and higher costs; start-up costs, inefficiencies, delays, and increased depreciation costs in connection with the start of production in new plants and expansions.
- Failure to have sufficient manufacturing capacity to make clinical supplies or commercial product in a timely and cost-competitive manner. Insufficient manufacturing capacity could delay clinical trials or limit commercial sale of marketed products.
- Health care reform, including reductions or changes in reimbursement available for prescription medications or other reforms.
- Difficulties in attracting and retaining key personnel, especially in areas where we have little experience such as sales and marketing.

As our scientific efforts lead to potentially promising new directions, both outside of recombinant protein therapies and into conditions or diseases outside of our current areas of experience and expertise, we will require additional internal expertise or external collaborations in areas in which we currently do not have substantial resources and personnel.

Other parties could allege to have blocking patents covering any of our product candidates in clinical and/or pre-clinical development. For example, we are aware of certain United States and foreign patents held by third parties relating to particular IL-4 and IL-13 receptors. In addition, we are aware of a European patent that pertains to the use of CNTF for the treatment of obesity.

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 one or more of our product candidates, which could severely harm our business.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or

discontinue the development of our products or pay license fees or royalties to take into account patent rights of third parties.

#### 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 estimate that a one percent change in interest rates would result in an approximately \$0.4 million change in the fair market value of our investment portfolio at March 31, 2003.

#### Item 4. Controls and Procedures

Within the 90 days prior to the date of this report (the "Evaluation Date"), we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined in Rules 13a-14(c) and 15d-14(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon the evaluation, our President and Chief Executive Officer along with our Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in timely alerting them to material information relating to Regeneron required to be included in our reports filed or submitted under the Exchange Act. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the Evaluation Date.

## PART II. OTHER INFORMATION

## Item 1. Legal Proceedings

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of its officers and directors in the United States District Court for the Southern District of New York. The complaints, which purport to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. We believe that the lawsuits are without merit.

## Item 6. Exhibits and Reports on Form 8-K

- (a) Exhibits
  - 10.23\* -- Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
  - 10.24\* -- Stock Purchase Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG and the Company.
  - 10.25 -- Registration Rights Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG and the Company.
  - 99.1 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.
  - Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.
- (b) Reports

Form 8-K, filed April 1, 2003: On March 28, 2003, we issued a press release announcing that we had signed a development and commercialization agreement with Novartis AG covering our IL-1 Trap, which is currently in Phase II clinical development for the treatment of rheumatoid arthritis. On March 31, 2003, we issued a press release announcing the preliminary results of our initial Phase III study evaluating AXOKINE in the treatment of obesity.

Form 8-K, filed April 16, 2003: On April 14, 2003, we issued a press release announcing the initial results of our Phase II trial evaluating AXOKINE for weight loss in overweight and obese people with type 2 diabetes.

Form 8-K, filed May 5, 2003: On May 5, 2003, we issued a press release announcing our first quarter 2003 financial and operating results.

#### 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.

Date: May 15, 2003

Regeneron Pharmaceuticals, Inc.

By: /s/ Murray A. Goldberg

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

#### Certifications

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 quarterly 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 quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

#### **Table of Contents**

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 quarterly 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 quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

By: /s/ Murray A. Goldberg

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

35

-----

COLLABORATION, LICENSE AND OPTION AGREEMENT

By and Between

NOVARTIS PHARMA AG,

NOVARTIS PHARMACEUTICALS CORPORATION

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of March 28, 2003

\_\_\_\_\_

# Page

ARTICLE I DEFINITIONS			
ARTICLE II COOPERATION 2.1 Scope of Cooperation 2.2 Compliance With Law 2.3 Diligence 2.4 Reservation of Rights. 2.5 Further Assurances and Transaction Approvals.	19 19 19 19 19 20		
ARTICLE III MANAGEMENT	20 20 21 22 23 26 26		
ARTICLE IV EXISTING PATENT AND KNOW-HOW RIGHTS; LICENSE GRANTS.         4.1 Regeneron License Grants Regarding Trap-1.         4.2 Novartis License Grants Regarding the IL-1 Antibody.         4.3 Regeneron License Grants Regarding Trap-2.         4.4 Technology Transfer.         4.5 Sublicenses.	27 27 28 28 28 29		
ARTICLE V DEVELOPMENT AND OPT-IN RIGHTS. 5.1 Pre-Phase III Development of the IL-1 Antibody. 5.2 Pre-Phase III Development of Trap-2. 5.3 IL-1 Antibody Opt-In Rights. 5.4 Trap-2 Opt-In Right. 5.5 Grant of Co-Development Rights. 5.6 Co-Development of IL-1 Products. 5.7 Co-Development Plans. 5.8 Co-Development Reports. 5.9 Loan Facilities for Trap-1 Product Development Costs.	29 29 30 31 31 33 33 33 33		
<pre>ARTICLE VI CO-COMMERCIALIZATION. 6.1 Grant of Co-Commercialization Rights. 6.2 Exceptions to the Grant of Co-Commercialization Rights. 6.3 Commercialization of IL-1 Products in Co-Marketing Countries. 6.4 Commercialization of IL-1 Products in Co-Commercialization Countries. 6.5 Co-Commercialization Plans. 6.6 Co-Commercialization Reports and Detailing Reports. 6.7 IL-1 Product Pricing and Pricing Approvals. 6.8 Booking of Sales and IL-1 Product Distribution. 6.9 Field Forces. 6.10 Detailing.</pre>	38 39 39 40 40 41 42 42 42 42 43		

# Page

6.11 6.12 6.13 6.14 6.15 6.16 6.17 6.18 6.19 6.20 6.21 6.22 6.23	Promotional Materials Promotional Claims/Compliance. Samples Cost of Field Sales Promotion. Managed Care and Institutional Customers. Shared Promotion Expenses Medical and Consumer Inquiries. Compliance with Laws. Phase IV Clinical Trials. Market Exclusivity Extensions. Non-Compete.	45 46 46 47 47 47 47 47 48 48 48 48
7.1 7.2 7.3 7.4 7.5	JINICAL AND REGULATORY AFFAIRS	51 51 52 52 52 53
8.1 8.2 8.3	MANUFACTURING AND SUPPLY Supply of Clinical Supply Requirements for Trap-1 Product Supply of Commercial Requirements for Trap-1 Product Supply of Clinical Supply Requirements and Commercial Requirements for IL-1 Antibody Product Supply of Clinical Supply Requirements and Commercial Requirements for Trap-2 Product	53 53 54 55 55
9.1 9.2 9.3 9.4 9.5 9.6 9.7 9.8 9.9	NIODIC REPORTS; PAYMENTS Periodic Reports. Funds Flow. Royalty. Upfront Payments and Milestone Payments. Revenue and Expenses in Co-Marketing Countries. Allocation of Costs and Expenses. Invoices and Documentation. Payment Currency. Late Payments. Taxes.	56 57 57 58 58 58 58 58 58 58 58
10.1	PUTE RESOLUTION Resolution of Disputes Arbitration of Legal Disputes	59 59 59

(ii)

# TABLE OF CONTENTS (continued)

# Page

ARTICLE XI TRADEMARKS AND CORPORATE LOGOS	61
11.1 Corporate Logos	61
11.2 Selection of Product Trademarks	61
11.3 Ownership of Product Trademarks	61
11.4 Prosecution, Maintenance and Enforcement of Product Trademarks	61
11.5 License to the Trap-1 and Trap-2 Product Trademarks	62
11.6 License to the IL-1 Antibody Product Trademark	62
11.7 Use of Corporate Names	63
ii./ Use of corporate names	63
ARTICLE XII NEWLY CREATED INVENTIONS	63
12.1 Ownership of Newly Created Intellectual Property	63
12.2 Prosecution and Maintenance of Fatent Rights.	64
12.2 Trosecution and maintenance of fatent Rights	04
ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION	65
13.1 Third Party Infringement Suits	65
13.2 Patent Marking	66
13.3 Third Party Infringement Claims	66
13.4 Amgen License.	67
15.4 Amgen License.	07
ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS	67
14.1 Books and Records.	67
14.2 Audits and Adjustments.	67
14.3 Accounting Standards	68
14.5 Accounting Standards	00
ARTICLE XV REPRESENTATIONS AND WARRANTIES	68
15.1 Due Organization, Valid Existence and Due Authorization	68
15.2 Intellectual Property	68
15.3 Disclaimer	69
ARTICLE XVI CONFIDENTIALITY	69
16.1 Confidential Company Information	69
16.2 Injunctive Relief	70
16.3 Publication of New Information	70
16.4 Other Publications.	71
10.4 Other Fullications	/ 1
ARTICLE XVII INDEMNITY	71
17.1 Indemnity and Insurance	71
17.2 Indemnity Procedure	72
	. 2
ARTICLE XVIII FORCE MAJEURE	72
ARTICLE XIX TERM AND TERMINATION	73
19.1 Term	73
19.2 Expiration of Term	73
19.3 Termination By Mutual Agreement in Special Circumstances	74
19.4 Termination Without Cause	75

(iii)

# Page

-	9.5	Termination For Material Breach	76 77
	9.7	Insolvency. Termination for Change of Control.	77
-			//
1	9.8	Effect of Termination for Material Breach, Insolvency, Change of Control	
		or Breach of Standstill Provisions	78
1	9.9	Survival of Obligations	78
ARTICLE XX	MISC	CELLANEOUS	79
	0.1	Governing Law	79
2	0.2	Waiver.	79
-	0.3	Notices.	79
2	0.4	Entire Agreement	79
2	0.5	Amendments	79
2	0.6	Headings	80
2	0.7	Severability	80
2	0.8	Registration and Filing of the Agreement	80
2	0.9	Assignment	80
2	0.10	Successors and Assigns	80
-	0 11	Counterparts.	80
2	0.12	Third-Party Beneficiaries.	80
-	0.13	Relationship of the Parties.	81
-	0.14	Limitation of Damages.	81
-	0.14	Non-Solicitation.	81
-	0.10		81
2	0.16	Hardship	81

(iv)

SCHEDULE	1	Target Profit Splits
SCHEDULE	2	Proportion of Detailing Efforts
SCHEDULE	3	Royalty
SCHEDULE	4	Shared Development Costs
SCHEDULE	5	Failure to Perform Details
SCHEDULE	6	Milestone Payments
SCHEDULE	7	Principles in Determining COGS
SCHEDULE	8	Preliminary Development Plan
SCHEDULE	9	First Consolidated Co-Development Budget
SCHEDULE	10	Non-Distributor Countries
SCHEDULE	11	Regulatory Tasks To Be Conducted By Novartis in U.S.
		for Trap-1 and Trap-2
SCHEDULE	12	Procedures for Adverse Event and Other Safety Data
		Exchange Notification and Reporting
SCHEDULE	13	Existing Licenses
SCHEDULE	14-18	[Intentionally Omitted]
SCHEDULE	19	Transition Arrangements
Part	A	Transition to Regeneron
Part	в	Transition to Novartis
SCHEDULE	20	Notices
EXHIBIT A		Form of Quality Agreement
		(V)

### COLLABORATION, LICENSE AND OPTION AGREEMENT

THIS COLLABORATION, LICENSE AND OPTION AGREEMENT ("Agreement"), dated as of March 28, 2003 (the "Effective Date"), is by and between NOVARTIS PHARMA AG, a corporation organized under the laws of Switzerland and having a principal place of business at Lichtstrasse 35, 4056 Basel, Switzerland ("Novartis"), NOVARTIS PHARMACEUTICALS CORPORATION of One Health Plaza, East Hanover, New Jersey ("NPC") and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Novartis and Regeneron referred to herein individually as a "Party" and collectively as the "Parties" and with NPC being a party to this Agreement for purposes of Section 9.4(a) only).

WHEREAS, Regeneron has certain rights in the applicable Territories in and to certain interleukin-1 trap molecules, and Regeneron intends to develop and commercialize the Trap-1 Product;

WHEREAS, Regeneron wishes to cooperate with another entity which provides expertise in the development, manufacture and commercialization of pharmaceutical products to Co-Develop, to manufacture and to Co-Commercialize and, in certain circumstances, Co-Market, the Trap-1 Product to Professionals, customers and the general public in certain countries in the Trap-1 Territory during the applicable Term;

WHEREAS, Novartis and its Affiliates possess expertise in developing, manufacturing and commercializing pharmaceutical products and has in place large and experienced regulatory and marketing teams;

WHEREAS, the Parties contemplate that enhanced sales resulting in mutual advantage may be realized by utilizing such expertise and Know-How of Novartis and its Affiliates and wish to Co-Develop and Co-Commercialize and, in certain circumstances, Co-Market, the Trap-1 Product to Professionals, customers and the general public in certain countries in the Trap-1 Territory during the applicable Term;

WHEREAS, Novartis and its Affiliates have certain rights in the applicable Territory in and to certain anti-interleukin-1 antibodies, and Novartis and certain of its Affiliates intend to develop, manufacture and commercialize the IL-1 Antibody Product;

WHEREAS, Novartis and its Affiliates are developing the anti-interleukin-1 antibodies known as AAL and ACZ;

WHEREAS, Novartis and its Affiliates wish to grant to Regeneron, and Regeneron wishes to accept, the right to elect to share in the Development and Commercialization of the IL-1 Antibody Product;

WHEREAS, Regeneron is also developing an interleukin-1 trap product, known as Trap-2; and

WHEREAS, Regeneron wishes to grant to Novartis and its Affiliates, and Novartis and its Affiliates wish to accept, the right to elect to share in the Development and Commercialization of the Trap-2 Product.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, 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:

"Adverse Reaction Reports" shall have the meaning set forth in Section 7.6(b).

"Affiliate" shall mean, with respect to any Person, any other 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. For purposes of this Agreement, in no event shall Novartis or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates.

"Agreement" shall have the meaning set forth in the introductory paragraph, including all Schedules.

"Alliance Manager" shall have the meaning set forth in Section 3.6.

"Allocable Overhead" shall have the meaning set forth in SCHEDULE 7.

"Alternate Marketing Channels" shall mean promotional services such as telemarketing, peer meetings, medical symposia, direct mail, internet marketing and electronic detailing, and other legally accepted promotional activities, whether directed to Professionals, customers or the public at large.

"Amgen License Agreement" shall mean the License Agreement dated as of June 26, 2002 among Amgen Inc., Immunex Corporation, and Regeneron, as it may be amended from time to time, a true and correct copy of which has previously been delivered to Novartis.

"Ancillary Agreement" shall mean any other agreement between the Parties pertaining to the Co-Development, production, technology transfer, and/or Co-Commercialization of IL-1 Products in the Co-Commercialization Countries during the applicable Term, which agreement shall have been expressly designated by the Parties as an "Ancillary Agreement" for purposes hereof.

"Annual Net Sales" shall mean, with respect to an IL-1 Product, Net Sales of such IL-1 Product during any Contract Year.

"Approval" shall mean, with respect to each IL-1 Product, any approval (excluding Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the manufacture, Development, Co-Commercialization, sale, storage or transport of such IL-1 Product in any Co-Commercialization Country, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

"BLA" shall mean, with respect to each IL-1 Product, a biologics license application filed with respect to such IL-1 Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

"Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, USA, or Basel, Switzerland, are authorized or required by Law to remain closed.

"Change of Control" shall mean, with respect to either Party, any of the following events: (i) any Person is or becomes the "beneficial owner" (as such term is used in Sections 12(d) and 13(d) of the Securities Exchange Act of 1934, as amended, except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all classes of capital stock then outstanding of such Pa such Party normally entitled to vote in elections of directors; (ii) such Party consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such Party, other than (A) a merger or consolidation which would result in the voting securities of such Party 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 such Party or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of such Party (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of such Party representing a majority of the combined voting power of such Party's then outstanding securities; or (iii) such Party conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly-owned Affiliate of such Person.

"Clinical Supply Cost" shall mean, with respect to Clinical Supply Requirements of a particular IL-1 Product, the manufacturing Party's Fully Burdened Manufacturing Cost (in this instance the definition of Fully Burdened Manufacturing Cost shall apply to Regeneron as a manufacturing party as well) for the particular IL-1 Product.

"Clinical Supply Requirements" shall mean the quantities of any IL-1 Product which are required by a Party or the Parties for the conduct of preclinical studies and Clinical Trials in connection with a Consolidated Co-Development Plan in order to obtain Approval of such IL-1 Product in any country in an applicable Territory and quantities of any IL-1 Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in any country in an applicable Territory.

-3-

"Clinical Trial" shall mean a Phase I Clinical Trial, Phase I/IIA Clinical Trial, Phase IIA Clinical Trial, Phase IIB Clinical Trial, Phase III Clinical Trial, Phase IIIB Clinical Trial, Phase IV Clinical Trial or combination thereof.

"Co-Brand" or "Co-Branding" shall mean, with respect to an IL-1 Product, in an applicable territory the marketing and promotion of such IL-1 Product under separate and distinct trademarks by each Party or its Affiliates in a Co-Branding Country pursuant to the applicable Country Co-Commercialization Plan, and where both brands are distributed and sold in such Co-Branding Country only by Novartis or its Affiliates.

"Co-Branding Country" shall mean each country in the applicable Territory in which Co-Promotion of IL-1 Products is not permitted under local Law and Co-Marketing is not required under local Law.

"Co-Commercialize" or "Co-Commercialization" shall mean Co-Branding and Co-Promoting, as defined in this Article I.

"Co-Commercialization Country" shall mean each Co-Promotion Country and Co-Branding Country in the applicable Territory.

"Co-Commercialization Provisions" shall have the meaning set forth in Section 6.1(c).

"Co-Development" shall mean the joint Development of IL-1 Products by the Parties, as described in Sections 5.5 to 5.8 inclusive, following: (a) the Effective Date with respect to Trap-1 Products; (b) the proper exercise of the IL-1 Antibody Opt-In Rights, with respect to IL-1 Antibody Products; and (c) the proper exercise of the Trap-2 Opt-In Rights, with respect to Trap-2 Products, and "Co-Develop" shall have a corresponding meaning.

"COGS" or "Cost of Goods Sold" shall mean, with respect to each IL-1 Product, the price of such IL-1 Product as agreed between the Parties pursuant to Section 8.2(a) and in accordance with the principles set forth in SCHEDULE 7 hereto.

"Collaboration Matters" shall have the meaning set forth in Section 3.1(c).

"Collaboration Purpose" shall have the meaning set forth in Section 3.1(b).

"Co-Market" or "Co-Marketing" shall mean, with respect to an IL-1 Product, the separate marketing and sale in a Co-Marketing Country of such IL-1 Product under separate and distinct trademarks.

"Co-Marketing Country" shall mean each country in the applicable Territory in which Co-Promotion and Co-Branding are not permitted under local Law, but in which Co-Marketing is permitted under local Law.

"Commercial Requirements" shall mean such quantities of any IL-1 Product as are required by a Party or the Parties to fulfill such Party's or Parties' commercial sales requirements with respect to such IL-1 Product in the applicable Territory.

"Commercialize" or "Commercialization" shall mean any and all activities directed to marketing, promoting, distributing, importing, offering for sale and/or selling an IL-1 Product, including pre-marketing (including market research and analysis, and health

-4-

economics), sampling, post-marketing drug surveillance and conducting Phase IIIB Clinical Trials and Phase IV Clinical Trials, other than those intended to support or maintain a Registration Filing for the particular IL-1 Product (including by way of example to support expanded labeling for such IL-1 Product or to satisfy requirements imposed by Regulatory Authorities in connection with Approvals for such IL-1 Product).

"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 with respect to the research, manufacture, Development or Commercialization of any IL-1 Product, 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 account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace (for this purpose treating another IL-1 Product as if it were owned by a Third Party), the patent and other proprietary position of the product, the likelihood of Approval given the regulatory structure involved, the profitability of the product, alternative products (for this purpose, treating another IL-1 Product as if it were owned by a Third Party) and other relevant factors. Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis, and it is anticipated that the level of effort will change over time, reflecting changes in the status of the Parties, the particular IL-1 Product and the market(s) involved. In evaluating "market potential," neither Party shall consider the profit sharing, milestone or other payments payable under this Agreement to the other Party.

"Committee" means any of the JSC and the JOC each as defined in this Article I and described in Article III (together with any other committee or sub-committee contemplated hereby or established in accordance with this Agreement or any Ancillary Agreement).

"Company Information" shall mean information or materials provided in connection with this Agreement or any Ancillary Agreement by either Novartis or Regeneron or their respective Affiliates to the other Party or its Affiliates, including, without limitation, by disclosure to any Committee, whether furnished before or after the Effective Date, including, without limitation, information and materials in relation to research, development, manufacturing, promotion, marketing, distributing and selling of IL-1 Products hereunder, and information and materials on substances, formulations, techniques, technology, equipment, data, reports, Know-How, sources for supply, patent position, business plans, sales management procedures and other general business and operational processes and procedures.

### 

"Consolidated Co-Commercialization Budget" shall mean, with respect to an IL-1 Product, the global annual budget(s) for all Co-Commercialization Countries as set forth in the Consolidated Co-Commercialization Plan approved by the Joint Steering Committee.

"Consolidated Co-Commercialization Plan" shall mean, with respect to an IL-1 Product, each annual global Co-Commercialization plan for such IL-1 Product approved by the Joint Steering Committee, including the related Consolidated Co-Commercialization

-5-

Budget, for the Co-Commercialization Countries, which shall include, inter alia, the total number of PDEs to be conducted by the Parties or their relevant Affiliates

"Consolidated Co-Commercialization Report" shall mean, with respect to an IL-1 Product, a written report setting forth in reasonable detail the marketing and promotional activities (other than PDEs) undertaken by the reporting Party and its Affiliates during the previous quarter in connection with the Consolidated Co-Commercialization Plan, together with a detailed project-level statement of Shared Promotion Expenses incurred by such quarter, including any necessary adjustments for previous quarters.

"Consolidated Co-Development Budget" shall mean, with respect to an IL-1 Product, the budget(s) approved by the Joint Steering Committee for the applicable Territory included in the Consolidated Co-Development Plan; provided, however, that [\*\*\*\*\*\*] \*\*\*\*\*

"Consolidated Co-Development Plan" shall mean, with respect to an IL-1 Product, each annual global Co-Development Plan for such IL-1 Product approved by the Joint Steering Committee, including the related Consolidated Co-Development Budget for the applicable Territory. With respect to the period from January 1, 2003 through December 31, 2003, the Preliminary Development Plan shall serve as the Consolidated Co-Development Plan, and the budget set forth as SCHEDULE 9 shall serve as the Consolidated Co-Development Budget, for such period.

"Consolidated Net Sales and Expense Report" shall mean, with respect to each IL-1 Product, a consolidated quarterly report prepared by Novartis setting forth in detail for each Region within the applicable Territory, the aggregate Net Sales, COGS, Shared Promotion Expenses and Development Costs in the Co-Commercialization Countries in such Region.

"Contract Sales Force" shall mean the services of sales representatives employed by a Third Party.

"Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2003, and each succeeding twelve (12) month period thereafter during the Term.

"Controlling Party" shall mean, with respect to the filing, prosecution and maintenance of a Joint Patent Right, Novartis, in the case of a Joint Patent Right that primarily relates to an IL-1 Antibody Product, and Regeneron, in the case of a Joint Patent Right that primarily relates to a Trap-1 Product or a Trap-2 Product.

"Co-Promote" or "Co-Promotion" shall mean, with respect to an IL-1 Product, the joint marketing and promotion of such IL-1 Product by the Parties (or their respective Affiliates), under the same trademark in each Co-Promotion Country pursuant to the applicable Country Co-Commercialization Plan, and the distribution and sale of such IL-1 Product in such Co-Promotion Country solely by Novartis or its Affiliates.

"Co-Promotion Country" shall mean each country included in the applicable Territory, other than the Co-Branding Countries and the Co-Marketing Countries.

"Country Co-Commercialization Budget" shall mean the budget(s) included in a Country Co-Commercialization Plan for a particular Co-Commercialization Country.

-6-

"Country Co-Commercialization Plan" shall mean the plan(s), including the related Country Co-Commercialization Budget, developed by the JOC or the applicable Joint Country Commercialization Sub-Committee (if any) for a particular Co-Commercialization Country, the main elements of which will be included in a Consolidated Co-Commercialization Plan approved by the JSC.

"Country Co-Commercialization Report" shall mean, with respect to an IL-1 Product, a written report setting forth in reasonable detail the marketing and promotional activities (other than PDEs) undertaken by a Party (or its relevant local Affiliates) during the previous guarter in connection with the applicable Country Co-Commercialization Plan, together with a detailed project-level statement of Shared Promotion Expenses incurred by such Party during such quarter in such Co-Commercialization Country, including any necessary adjustments for previous quarters.

"Country Net Sales and Expense Report" shall mean, with respect to each IL-1 Product and each Co-Commercialization Country, a report prepared by Novartis setting forth the aggregate Net Sales, COGS, Shared Promotion Expenses and Development Costs with respect to such IL-1 Product in such Co-Commercialization Country in local currency.

"Damages" shall have the meaning set forth in Section 17.1(a).

"Default Interest Rate" shall have the meaning set forth in Section

9.9.

"Detail" or "Detailing" shall mean a face-to-face meeting in an individual or group practice setting, between a Qualified Sales Representative of a Party or its Affiliate, on the one hand, and a Professional, on the other hand, during which a Primary Product Presentation or a Secondary Product Presentation is made to such Professional relating to an IL-1 Product; provided that such meeting is generally consistent with and in accordance with the procedures and policies customarily employed by such Party's sales force responsible for performing such activities for the majority of its other major marketed pharmaceutical products (if any).

"Detailing Report" shall have the meaning set forth in Section 6.6.

"Develop" or "Development" shall mean (a) preclinical and clinical drug development activities, including, without limitation, test method development and stability testing, assay development and audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis, Clinical Trials (except for Phase IIIB Clinical Trials and Phase IV Clinical Trials conducted for purposes other than to support or maintain a Registration Filing for the particular IL-1 Product, including by way of example to support expanded labeling for such IL-1 Product or to satisfy requirements imposed by Regulatory Authorities in connection with Approvals for such IL-1 Product) and regulatory affairs, product approval and registration and (b) research and development of the applicable drug products and drug substances.

"Development Costs" shall mean, with respect to any IL-1 Product, expenses and other costs, including Regulatory Expenses, incurred by or on behalf of a Party in connection with the Development of such IL-1 Product in accordance with the applicable approved Consolidated Co-Development Plan and Consolidated Co-Development Budget, including, without limitation, the costs of Clinical Trials, the preparation, collation and/or validation of data from such Clinical Trials and the preparation of medical writing and publishing;

-7-

provided that Development Costs shall include the cost of Phase IIIB Clinical Trials and Phase IV Clinical Trials only if they are intended to support or maintain a Registration Filing for the particular IL-1 Product (including by way of example to support expanded labeling for such IL-1 Product, or to satisfy requirements imposed by Regulatory Authorities in connection with Approvals for such IL-1 Product). Without limitation of the generality of the foregoing, Development Costs shall include:

> (a) all Out-of-Pocket Costs incurred by the Parties or their Affiliates, including payments made to Third Parties with respect to any of the foregoing;

(b) the full personnel cost of internal scientific and technical personnel engaged in such efforts, which costs shall be determined based on the FTE Rate or such other basis as may otherwise be agreed by the Parties;

(c) the costs of Clinical Supply Requirements (including, without limitation, Clinical Supply Costs) for such efforts as agreed in the applicable approved Consolidated Co-Development Plan;

(d) the costs and expenses incurred in connection with formulation development, manufacturing process development and validation, manufacturing scale-up and start-up, stability testing and quality assurance/quality control development (in each case, to the extent not included in COGS); and

(e) any other costs or expenses included in the applicable Consolidated Co-Development Budget contained in the applicable approved Consolidated Co-Development Plan.

Notwithstanding any other provision of this Agreement, Development Costs shall not include any costs or expenses incurred prior to: (i) January 1, 2003 (other than Clinical Supply Costs incurred in 2002 relating to Phase IIB Clinical Trials ongoing in 2003); (ii) the proper exercise of the IL-1 Antibody Opt-In Rights by Regeneron, with respect to Development of IL-1 Antibody Products; or (iii) the proper exercise of the Trap-2 Opt-In Rights by Novartis, with respect to Development of Trap-2 Products.

"Distributor" shall mean any Third Party contractually engaged by Novartis to market and/or sell the IL-1 Product in the relevant Co-Commercialization Country, where the cost of such Third Party's services is not greater than that set forth in the applicable Country Co-Commercialization Budget included in the applicable Country Co-Commercialization Plan.

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

"End of Phase II Development" shall mean the date on which the final report becomes available following completion of the first Phase IIB Clinical Trial (or Phase IIA Clinical Trial if such Clinical Trial is the Clinical Trial immediately preceding initiation of a Phase III Clinical Trial) for the IL-1 Antibody or Trap-2, as applicable, regardless of the indication for which such Phase IIB Clinical Trial is conducted.

"EU" shall mean the European Union Member States, as they exist from time to time, comprising, as of the Effective Date, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and the

-8-

United Kingdom, and in any event, including at a minimum, Germany, France and the United Kingdom.

"Europe" shall mean every country in the EU and Switzerland.

"Exclusive Country" shall mean each country agreed between the Parties pursuant to Section 6.2(b), if any.

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

"Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Novartis.

"Existing Licenses" shall mean the agreements listed in SCHEDULE 13.

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

"Final Approval" shall mean, with respect to any IL-1 Product: (a) in relation to the United States, receipt of the official approval letter from the FDA approving the BLA, with respect to such IL-1 Product or any supplemental BLA, as applicable; and (b) in relation to any country in Europe, receipt of the written decision of the appropriate Regulatory Authority granting marketing authorization for such IL-1 Product.

"First Commercial Sale" shall mean, with respect to an IL-1 Product in a country, the first sale of such IL-1 Product by a Party or one of its Affiliates or sublicensees to a Third Party in accordance with the applicable Laws of such country on arm's length commercial terms which are reasonably expected to be substantially similar to future terms of sale of such IL-1 Product to Third Parties for commercial use by patients in such country. Sales for test marketing, Clinical Trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

"Force Majeure" shall have the meaning set forth in Article XVIII.

"FTC" means the United States Federal Trade Commission.

"FTE" shall mean a full-time equivalent person year (\*) of scientific, technical or managerial work on studies or activities performed in accordance with the applicable Consolidated Co-Development Plan, in connection with obtaining Approvals for the IL-1 Products or, in certain circumstances, its connection with the Commercialization of an IL-1 Product.

"Fully Allocated Costs" shall mean, with respect to an activity, all direct and indirect costs and overhead allocable to the conduct of such activity in accordance with GAAP or IAS, as applicable (depending on how the entity conducting such activity maintains its accounting books and records), including, without limitation, costs of raw materials, supplies,

-9-

other resources consumed in the conduct of such activity, rent, real estate depreciation, utilities, insurance, equipment lease payments, equipment depreciation and labor.

"Fully Burdened Manufacturing Costs" shall have the meaning set forth in SCHEDULE 7.

 $\ensuremath{\ensuremath{\mathsf{GAAP}}}\xspace$  shall mean generally accepted accounting principles in the United States.

"Global Harmonized Clinical Trial Guidelines" shall mean the guidelines, applicable to pre-clinical trials and Clinical Trials, which are developed by the ICH, as enacted in Law by ICH member countries and those adherent countries which are not formal parties to the ICH but which adhere to the tenets of the ICH process in whole or in part.

"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.

"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.

"ICC Court" shall have the meaning set forth in Section 10.2(b).

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

"IL-1" means the cytokine, interleukin-1.

"IL-1 Antibody Opt-In Payment" shall mean: [\*].

"IL-1 Antibody Opt-In Rights" shall mean the rights set forth in Section 5.3.

"IL-1 Antibody Product" shall mean one or more pharmaceutical products for human and/or animal use which include the IL-1 Antibody as an active ingredient, alone or in combination with one or more other active ingredients, for all indications.

"IL-1 Antibody Territory" shall mean NAFTA.

"IL-1 Products" shall mean: (a) any Trap-1 Product; and (b) in the event that Novartis properly exercises the Trap-2 Opt-In Rights, any Trap-2 Product; and (c) in the event that Regeneron properly exercises the IL-1 Antibody Opt-In Rights, any IL-1 Antibody Product in each case, subject to Article XIX (including SCHEDULE 19), for so long as this Agreement has not been terminated with respect to such IL-1 Product.

"IND" shall mean an Investigational New Drug Application filed with the FDA.

-10-

"Indemnified Party" shall have the meaning set forth in Section 17.2(a).

"Indemnifying Party" shall have the meaning set forth in Section 17.2(a).

"International Accounting Standards" or "IAS" shall mean international accounting standards (IAS), as published from time to time by the International Accounting Standards Committee.

"IPSC" shall have the meaning set forth in Section 3.1(a).

"Joint Invention" shall have the meaning set forth in Section 12.1(b).

"Joint Operating Committee" or "JOC" shall mean the Joint Operating Committee, as described in Section 3.4.

"Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.

"Joint Steering Committee" or "JSC" shall mean the Joint Steering Committee, as described in Section 3.2.

"Know-How" shall mean any and all proprietary technical information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings, and other information (whether or not patentable) which are now or hereafter during the term of this Agreement owned by, licensed to or otherwise held by a Party or its Affiliates with the rights to license or sublicense the same and that relate to an IL-1 Product or the Development, manufacture, use, offer for sale or sale thereof.

"Launch" shall mean, with respect to an IL-1 Product in a country, the First Commercial Sale of such IL-1 Product in such country after receipt of all required Approvals, and, if applicable, Pricing Approval and import approval.

"Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority in the applicable Territory.

"Lead Regulatory Party" shall mean, with respect to each IL-1 Product, whichever of Novartis or Regeneron has been designated hereunder as having responsibility for preparing, prosecuting and maintaining Approvals and Registration Filings relating to such IL-1 Product, and for related regulatory duties.

"Legal Dispute" shall mean any dispute, controversy or claim related to compliance with this Agreement or any Ancillary Agreement or the validity, breach, termination or interpretation of this Agreement or any Ancillary Agreement, but shall not include any matter to be determined pursuant to Article III, except to the extent such matter constitutes a dispute, controversy or claim related to compliance, with or the validity, breach, termination or interpretation of any provision of Article III.

"Managed Care and Institutional Customers" shall mean managed care, long-term care, senior care, health system, hospital, group purchasing, government and physician similar practice group customers in the Co-Commercialization Countries, together with such other types of similar customers as may be agreed by the JOC from time to time on a country-by-country basis.

"Market Exclusivity Period" shall mean, with respect to each IL-1 Product in each Co-Commercialization Country, that period of time during which (a) a Party(ies) has the

-11-

exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to market, price and sell such IL-1 Product in such country, and (b) no generic equivalent of such IL-1 Product is marketed in such country.

"NAFTA" shall mean the United States, Canada and Mexico.

"Net Sales" shall mean, with respect to an IL-1 Product, the gross invoiced sales price of such IL-1 Product billed by or on behalf of Novartis or its Affiliates to Third Parties on sales of an IL-1 Product in bona fide arm's length transactions in the Co-Commercialization Countries, less the following deductions, determined in accordance with Novartis' standard accounting methods as generally and consistently applied by Novartis, to the extent included in the gross invoiced sales price for such IL-1 Product or otherwise directly paid or incurred by such Novartis, its Affiliates or Distributors with respect to the sale of such IL-1 Product:

> normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of such IL-1 Product;

(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 such IL-1 Product;

(d) Third Party cash rebates and chargebacks related to sales of the finished IL-1 Product, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) tariffs, duties, excise, sales, value-added or other taxes (other than taxes based on income);

(g) cash discounts for timely payment;

(h) delayed ship order credits;

 discounts pursuant to indigent patient programs and patient discount programs, including, without limitation,

(k) any other specifically identifiable costs or charges included in the gross invoiced sales price of such IL-1 Product falling within categories substantially equivalent to those listed above.

Sales from Novartis to its Affiliates 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 Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of an IL-1 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. In the event that any IL-Product includes one or more active ingredients other than Trap-1, Trap-2 or the IL-1 Antibody, then, prior to Launch of such IL-1 Product, the Parties

-12-

shall agree, through the JSC, the appropriate method for accounting for sales of such IL-1 Product. All discounts, credits, rebates, reductions, chargebacks, and similar deductions described above shall be consistent with policies and parameters approved in advance by the JSC or the applicable Country Co-Commercialization Committee, if any.

"New Information" shall mean any and all ideas, inventions, writings, discoveries, improvements, not generally known to the public, which may arise or be conceived or developed by either Party or jointly during the term of this Agreement which relates to any IL-1 Product.

"New License" shall mean any license, other than Existing Licenses, required for the manufacture, Development or Commercialization of any IL-1 Product and approved by the Intellectual Property Sub-Committee.

"Novartis" shall have the meaning set forth in the introductory paragraph.

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

"Novartis Patent Rights" shall mean those Patent Rights which are owned by or licensed (with the right of sublicense) to Novartis or any of its Affiliates (other than pursuant to this Agreement or any Ancillary Agreement) and which include at least one claim which would be infringed by the manufacture, use, sale, offer for sale or import of an IL-1 Product at any time during the applicable Term for such IL-1 Product.

"Novartis Sole Inventions" shall have the meaning set forth in Section 12.1(a).

"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) by either Party and/or its Affiliates.

"Party" or "Parties" shall have the meaning set forth in the introductory paragraph.

"Patent Application" shall mean any application for a Patent.

"Patent Rights" shall mean unexpired Patents and Patent Applications.

"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.

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

"Phase I Clinical Trial" shall mean a clinical study of an IL-1 Product in human volunteers with the endpoint of determining initial tolerance, safety and/or pharmacokinetic

-13-

information in single dose, single ascending dose, multiple dose and/or multiple ascending dose regimens.

"Phase I/IIA Clinical Trial" shall mean (a) a Phase I Clinical Trial and a Phase IIA Clinical Trial, collectively, or (b) a single clinical study meeting the requirements of a Phase I Clinical Trial and a Phase IIA Clinical Trial.

"Phase IIA Clinical Trial" shall mean a clinical study of an IL-1 Product in patients to determine initial dose ranging tolerability and safety in single dose, single ascending dose, multiple dose and/or multiple ascending dose regimens.

"Phase IIB Clinical Trial" shall mean a clinical study of an IL-1 Product in patients to definitively determine appropriate dose ranging tolerability and safety.

"Phase III Clinical Trial" shall mean a clinical study in patients which protocol is designed to ascertain efficacy and safety of an IL-1 Product for the purpose of preparing and submitting a Registration Filing to the competent Regulatory Authority in a particular country in the applicable Territory.

"Phase IIIB Clinical Trial" shall mean a Phase III Clinical Trial commenced before receipt of Approval in the jurisdiction where such trial is being conducted, but which is not required for receipt of Approval and is conducted primarily for the purpose of IL-1 Product support (i.e., providing additional drug profile data).

"Phase IV Clinical Trial" shall mean a clinical study initiated in a country after receipt of Final Approval for an IL-1 Product in such country.

"Plan" shall mean any Consolidated Co-Commercialization Plan, any Country Co-Commercialization Plan, any Consolidated Co-Development Plan or other plan approved through the Committee process relating to the Co-Development or Co-Commercialization of an IL-1 Product under this Agreement.

"Preliminary Development Plan" shall have the meaning set forth in Section 5.7.

"Prescription Drug Marketing Act" or "PDMA" shall mean the Prescription Drug Marketing Act of 1987, as amended from time to time.

"Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for an IL-1 Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the applicable Territory where governmental authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

"Primary Product Presentation" shall mean a full product presentation during a call in which key messages related to an IL-1 Product are presented in the first position and in a balanced manner consistent with the terms of this Agreement, and [\*\*\*\*\*\*\*\*\*\*\*\*\*\*].

"Product Trademark" shall mean, with respect to each IL-1 Product, the trademark selected by the JSC for use on such IL-1 Product and/or accompanying logos, trade dress and/or indicia of origin, in each case as selected by the JSC.

-14-

"Professionals" shall mean physicians and other health care practitioners who are permitted under the Laws of the Co-Commercialization Country in which they work to prescribe the IL-1 Product.

"Promotional Materials" shall mean, with respect to each IL-1 Product, promotional, advertising, communication and educational materials relating to such IL-1 Product for use in connection with the marketing, promotion and sale of such IL-1 Product in the applicable Territory, and the content thereof, and shall include, without limitation, logos, slogans, trade dress, website content and artwork, promotional literature, product support materials and promotional giveaways.

"Publishing Party" shall the meaning set forth in Section 16.3.

"Regeneron" shall have the meaning set forth in the introductory paragraph.

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

"Regeneron Patent Rights" shall mean those Patent Rights which are owned by or licensed (with the right of sublicense) to Regeneron or any of its Affiliates (other than pursuant to this Agreement or any Ancillary Agreement) and which include at least one claim which would be infringed by the manufacture, use, sale, offer for sale or import of an IL-1 Product at any time during the applicable Term for such IL-1 Product, and for the avoidance of doubt, Regeneron Patent Rights include any Patent Rights arising from the Phase IIA or IIB Clinical Trials described in Section 2.4(c).

"Regeneron Sole Inventions" shall have the meaning set forth in Section 12.1(a).

"Region" shall mean each of NAFTA, Europe and the Rest of World.

"Registration Filing" shall mean, with respect to each IL-1 Product, the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any marketing authorization application, supplementary application or variation thereof, BLA, or any equivalent applications in any Co-Commercialization Country.

"Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing, pricing and/or sale of any IL-1 Product in a country in the Territory, including, without limitation, FDA in the United States and EMEA in Europe.

"Regulatory Expenses" shall mean, with respect to an IL-1 Product, all Out-of-Pocket Costs and Fully Allocated Costs incurred by or on behalf of a Party in connection with the preparation and filing of Registration Filings and the maintenance of Approvals.

"Rest of World" shall mean, with respect to Trap-1 and Trap-2, all countries in the applicable Territory except for NAFTA and Europe.

"Rules" shall have the meaning set forth in Section 10.2(a).

-15-

"Sales Infrastructure Elements" shall mean each of the following: (a) a sales force automation system through which Qualified Sales Representatives can record calls electronically, receive email communications and reports, view sales reports and download physician targets and lists; (b) a sample accountability system that meets the requirements of Section 6.14 and that complies with all applicable Laws; (c) a sales training department that is responsible for providing general sales training and product training to Qualified Sales Representatives; (d) a department responsible for the design and administration of the applicable Party's sales incentive plan; (e) a voice mail system; (f) a system for sales reporting and analysis; (g) a sales administration and operations department that handles, among other things, fleet management; (h) a department that establishes and maintains territory alignments consistent with target professionals lists; (i) an electronic roster system that tracks sales force vacancy, turnover, demographics and territory occupancy; and (j) an electronic field expense reporting system.

"Severed Clause" shall have the meaning set forth in Section 20.7.

"Shared Promotion Expenses" shall mean, with respect to each IL-1 Product, Out-of-Pocket Costs and other costs (in the case of personnel costs for personnel directly involved in the marketing or promotional activities, determined based on the FTE Rate or such other basis as may otherwise be agreed by the Parties) which are incurred by a Party or any of its Affiliates to the extent consistent with the Consolidated Co-Commercialization Budget included in the then applicable Consolidated Co-Commercialization Plan and related to the Co-Commercialization of such IL-1 Product, including, without limitation, costs in the following categories:

(a) costs incurred in promoting and marketing such IL-1
 Product, including without limitation, advertising (including agency fees), market research, patient-oriented promotions, meetings, pre-Launch activities and expenses relating to launch of the IL-1
 Product, and managed markets/health authority liaisons (but excluding Detailing expenses);

(b) amounts repaid or credited for bad debts;

(c) costs associated with post-marketing drug safety surveillance;

 (d) medical affairs costs, and costs associated with medical/scientific liaisons (including regional scientific directors), medical education and publications, professional symposia, advisory boards, speaker and activity programs;

(e) costs of Phase IV Clinical Trials in the Co-Commercialization Countries (excluding costs associated with any Phase IV Clinical Trials intended to support or maintain a Registration Filing for such IL-1 Product, including by way of example to support expanded labeling for such IL-1 Product, or to satisfy requirements imposed by Regulatory Authorities in connection with Approvals for such IL-1 Product, all of which are included in Development Costs) and pharmacoeconomic studies;

-16-

(f) the cost of samples;

(g) costs of materials and programs for the training of sales force, regional sales management and marketing management;

 (h) costs of Promotional Materials, telemarketing, e-marketing, field and headquarters' grants, exhibits, direct mail and sample alternative programs;

(i) costs associated with global sales force training agreed by the JOC; provided, however, that each Party will train its own sales force (and that of its Affiliates) at its own expense;

(j) amounts paid by way of milestones or royalties due under any Existing License or New License with respect to sales of such IL-1 Product,

(k) amounts paid to a Third Party in a Co-Commercialization Country as a result of either Party, with the approval of the Intellectual Property Sub Committee, executing an agreement, including but not limited to a license agreement, with a Third Party in order to obtain freedom to operate with respect to such IL-1 Product in such Co-Commercialization Country; and

(1) amounts paid, whether in damages or by a settlement approved by the IPSC, to a Third Party in a Co-Commercialization Country as a result of any allegation of infringement by any Party of a Third Party patent by the manufacture, Development or Commercialization of such IL-1 Product.

The foregoing shall not include any Out-of-Pocket Costs or other costs which (i) are incurred prior to the Effective Date, (ii) are incurred in connection with the manufacture of any IL-1 Product, or (iii) have been included in Development Costs or Regulatory Expenses.

"Shortfall Party" shall have the meaning set forth in Section 6.10(d).

"Sole Inventions" shall have the meaning set forth in Section 12.1(a).

"Stock Out Event" shall have the meaning set forth in Section 8.2(d).

"Stock Purchase Agreement" shall mean the Stock Purchase Agreement between the Parties dated as of the date hereof, together with the Registration Rights Agreement contemplated thereby.

"Strategic Plan" shall mean the [\*\*\*\*\*\*\*\*\*\*] strategic plan, developed by the JOC and approved by the JSC, setting forth the Parties' strategies for optimizing the commercial value of the IL-1 Products.

"Target Profit Split" shall mean, with respect to each IL-1 Product, the applicable target profit splits set forth on SCHEDULE 1.

"Technology Transfer Agreement" shall mean the agreement described in Section 4.4(b).

"Term" shall have the meaning set forth in Section 19.1.

-17-

"Terminated Product" shall have the meanings set forth in Sections 19.2, 19.4 and 19.8, as applicable.

"Territory" shall mean: (a) with respect to Trap-1 Products, the Trap-1 Territory; (b) with respect to IL-1 Antibody Products, the IL-1 Antibody Territory; and (c) with respect to Trap-2 Products, the Trap-2 Territory.

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

"Trap-1 Product" shall mean one or more pharmaceutical products for human and/or animal use which include Trap-1 as an active ingredient, alone or in combination with one or more other active ingredients, for all indications.

"Trap-1 Territory" shall mean all the countries of the world, excluding Japan.

"Trap-2 Opt-In Rights" shall mean the rights set forth in Section 5.4.

"Trap-2 Product" shall mean one or more pharmaceutical products for human and/or animal use which include Trap-2 as an active ingredient, alone or in combination with one or more other active ingredients, for all indications.

"Trap-2 Territory" shall mean all the countries of the world, excluding Japan.

"Trial Success Criteria" shall mean the indicia of success in a Clinical Trial: (a) set forth in the Preliminary Development Plan (as may be amended from time to time in accordance with this Agreement) with respect to the Phase IIB Clinical Trial for rheumatoid arthritis ongoing at the Effective Date with respect to Trap-1, and (b) with respect to any other Clinical Trial, as agreed by the Parties through the JSC prior to the commencement of such Clinical Trial.

"United States" or "U.S." shall mean the United States of America, including its territories and possessions and its military bases and commissaries wherever located in the applicable Territories, the District of Columbia and Puerto Rico.

-18-

# ARTICLE II

#### COOPERATION

2.1 Scope of Cooperation. The Parties agree to cooperate in good faith under this Agreement and any Ancillary Agreements to effectively and efficiently Develop and Commercialize IL-1 Products in the Co-Commercialization Countries in such a manner as to optimize the commercial potential of IL-1 Products. To achieve these goals, the Parties wish to provide for: (a) the joint worldwide (excluding Japan) Development of IL-1 Products; (b) the Co-Promotion of IL-1 Products in the Co-Promotion Countries; (c) the Co-Branding of IL-1 Products in the Co-Branding Countries; (d) the Co-Marketing of IL-1 Products in the Co-Marketing Countries; and (e) the manufacture of IL-1 Products within the Territory by Novartis (for greater clarity, Novartis will or will have manufactured the IL-1 Products, however, Regeneron will manufacture the Clinical Supply Requirements for the Trap-1 Product through the earlier of the date of first Launch of a Trap-1 Product or the date that Novartis is capable of producing such Clinical Supply Requirements following the technology transfer referred to in Section 8.2(a)). For purposes thereof, the Parties shall establish various Committees as set forth in Article III of this Agreement to oversee the Development and Commercialization of IL-1 Products, and each Party shall, subject to the terms and conditions set forth in Article XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary confidential Company Information and such other information as may be reasonably required for the Parties to operate effectively and efficiently under this Agreement and any applicable Ancillary Agreement.

2.2 Compliance With Law. Both Novartis and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement, any applicable Ancillary Agreement and any then-applicable Plans (including, without limitation, the deployment of their respective sales forces) in an effort to Develop, manufacture, market and Detail IL-1 Products effectively in the Co-Commercialization Countries and 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 Diligence. Subject to the terms of this Agreement, each Party (and its Affiliates) shall diligently work to fulfill all responsibilities assigned to it under this Agreement, any applicable Ancillary Agreement and any then-applicable Plans.

2.4 Reservation of Rights.

(b) Trap-1 and Trap-2. With respect to each of Trap-1 and Trap-2, all rights not specifically granted herein to Novartis are expressly reserved to Regeneron.

(c) Limitation on Exercise of Rights Outside of Collaboration. Notwithstanding the foregoing, Novartis and Regeneron agree that, with effect from: (a) the Effective Date, with respect to Trap-1; (b) the proper exercise by Regeneron of the IL-1 Antibody Opt-In Rights, with respect to the IL-1

-19-

Antibody; and (c) the proper exercise by Novartis of the Trap-2 Opt-In Rights, with respect to Trap-2, and in each case, for so long as this Agreement remains in effect with respect to such IL-1 Product, neither it nor any of its Affiliates, either alone or through any Third Party, shall, for the term of the Agreement with respect to such IL-1 Product, Develop or Commercialize the applicable IL-1 Product in the applicable Territory, except pursuant to this Agreement; provided, however, that Regeneron may, at its option and at its sole expense, conduct additional (i.e., not contemplated by the Preliminary Development Plan) Phase IIA and Phase IIB Clinical Trials with respect to Trap-1 or Trap-2. In the event that Regeneron conducts any such additional Phase IIA or Phase IIB 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 by Regeneron to Novartis pursuant to this Agreement, and except as expressly set forth in the foregoing proviso, for so long as this Agreement remains in effect with respect to such IL-1 Product, the Trap-1 Product may only be Developed and Commercialized pursuant to the Agreement. For the avoidance of doubt, no additional consideration shall be payable by Novartis with respect to the conduct of any such Clinical Trial, or the rights granted herein with respect to any results, Know-How or Patent Rights generated in or arising from any such Clinical Trial.

2.5 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use all Commercially Reasonable Efforts to (i) after the Effective Date, 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, and (ii) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement and (iii) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions or changes suggested in connection therewith. Each Party will furnish all information required for any applicable Laws in connection with the transactions contemplated by this Agreement. For the avoidance of doubt, nothing in this Section 2.5, shall oblige either Party or its Affiliates to seek or obtain Approval for any IL-1 Product in any jurisdiction.

# ARTICLE III

#### MANAGEMENT

### 3.1 Committees/Management.

(a) The Parties agree to establish, for the purposes specified herein and/or in any applicable Ancillary Agreement, a Joint Steering Committee, a Joint Operating Committee and, as sub-committees of the Joint Operating Committee, a U.S. Joint Commercialization Committee, a Finance Sub-Committee and an Intellectual Property Sub-Committee ("IPSC"). The Parties may also agree, through the Joint Operating Committee, to

-20

establish, as sub-committees of the Joint Operating Committee, a Joint Development Sub-Committee, a Joint Regulatory Sub-Committee, a Joint Commercialization Sub-Committee, and, for each other Co-Commercialization Country, a Country Joint Commercialization Sub-Committee. Each Party shall bear its own costs associated with its participation in the Committees, and such costs shall not be included in the Development Costs or Shared Promotion Expenses.

(b) Each of the Committees and the Executive Officers shall exercise their decision-making authority hereunder in good faith and in a commercially reasonably manner for the purpose of optimizing the commercial potential of and financial returns from the IL-1 Products without regard to any other pharmaceutical product including, without limitation, any Trap-1 Product, IL-1 Antibody Product, or Trap-2 Product which has not been elected or for which this Agreement has been terminated with respect to such product in Development or being Commercialized or sold by or through a Party (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 or any of the Ancillary Agreements, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 The Joint Steering Committee.

(a) Composition. The Joint Steering Committee (the "JSC") shall be established by the Parties to supervise the performance of the Parties hereunder and shall be comprised of six (6) members consisting of senior leadership executives of Novartis and Regeneron who, in the case of Novartis, are responsible for global marketing and clinical development and, in the case of Regeneron, including those who have responsibility for marketing and clinical development. Promptly, but in no event more than thirty (30) days after the Effective Date, Novartis shall appoint three (3) representatives and Regeneron shall appoint three (3) representatives at Regeneron shall appoint three (3) representatives to the JSC. A Party may change any of its representatives at any time if a new person is appointed to any of the foregoing positions by giving written notice to the other Party. A JSC member may not, concurrently with JSC membership, be a member of any other Committee.

(b) Chairperson of the JSC. Novartis will designate the initial chairperson of the JSC, and the right to designate the JSC chairperson shall rotate between Novartis and Regeneron at the end of each calendar year. The chairperson of the JSC shall be: (i) entitled to set meeting agendas; provided that the agenda shall include any matter reasonably requested by either Party; (ii) required to call emergency meetings of the JSC at the request of a Party; and (iii) required, at the request of either Party, to present JSC disputes that have been unresolved for thirty (30) days to the Executive Officer of Regeneron, pursuant to Section 3.7. The JSC chairperson shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JSC.

(c) Meetings of the JSC. The JSC shall meet whenever any member of the JSC shall make such a request in writing to the chairperson (including a request by a Party for

-21-

an emergency meeting as contemplated by Section 3.2(b) above) or whenever a matter is referred to the JSC by the JOC pursuant to Section 3.7; provided, however, that the JSC shall in no event meet less frequently than once per year. Decisions of the JSC shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided that no such vote shall be valid unless each Party is represented by at least one member either by proxy or actual presence at the meeting at which the vote is taken. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member of the JSC to attend meetings where appropriate (e.g., the Alliance Managers, representatives of regulatory affairs or outside consultants). Such additional participants shall not be deemed a member of the JSC, nor shall they have any rights or responsibilities of a

(d) Authority of the JSC. Subject to Section 3.7, the JSC shall have the final decision-making authority with respect to all matters within the jurisdiction of any of the Committees established pursuant to this Agreement or any of the Ancillary Agreements which are referred to the JSC for determination or resolution. The JSC shall exercise this authority in good faith and in accordance with this Agreement, all decisions shall have a reasonable basis and any such decision shall be binding upon the Parties, without limitation, however, to the Parties' rights and remedies with respect to any Legal Dispute.

3.3 Responsibilities of the JSC. The responsibilities of the JSC shall be exercised consistent with this Agreement and shall include, but shall not be limited to, the following:

 (a) coordinating Strategic Plans for optimizing the Development and the commercial value of IL-1 Products in the Co-Commercialization Countries;

(b) approve target profiles for particular IL-1 Products;

(c) reviewing and approving on a timely annual basis Strategic Plans, Consolidated Co-Commercialization Plans (including related Consolidated Co-Commercialization Budgets) and Consolidated Co-Development Plans (including related Consolidated Co-Development Budgets) prepared by the JOC;

(d) approving Product Trademarks for each of the IL-1 Products;

(e) reviewing the efforts of the Parties in performing their respective Co-Development and Co-Promotion and Co-Branding activities, as applicable, in the Co-Commercialization Countries;

(f) % f(f) considering and acting upon such other matters as are specified in this Agreement; and

(g) attempting in good faith to resolve any disputes referred to it by the Joint Operating Committee.

3.4 Joint Operating Committee.

(a) Composition. The Joint Operating Committee ("JOC") shall be established by the Parties to, among other things, prepare and, to the extent provided herein, submit to the JSC for approval consolidated Development, regulatory, promotion and

-22-

marketing plans for the IL-1 Product in the Co-Commercialization Countries. The JOC shall be comprised of eight (8) members consisting of the senior executives of Novartis and Regeneron who, in the case of Novartis, are responsible for global marketing and clinical development and, in the case of Regeneron, including those who have responsibility for marketing and clinical development. Promptly after the Effective Date, Novartis and Regeneron will each appoint four (4) appropriate representatives to the JOC; provided that each Party must appoint, as one of its representatives on the JOC, its Alliance Manager. A Party may change any of its representatives at any time by giving written notice to the other Party but the replacement representative must also be a senior executive from Novartis or Regeneron (with appropriate expertise to replace the outgoing member). The total number of JOC members may be changed by unanimous vote of the JOC from time to time as appropriate; provided that the JOC shall in all cases be comprised of an equal number of members from each of Novartis and Regeneron.

(b) Chairperson of the JOC. Regeneron will designate the initial chairperson of the JOC, and the right to designate the JOC chairperson shall rotate between Novartis and Regeneron at the end of each calendar year. The JOC chairperson shall be: (i) entitled to set meeting agendas; provided that the agenda shall include any matter reasonably requested by either Party; (ii) required to call emergency meetings of the JOC at the request of a JOC member; and (iii) required, at the request of either Party, to present JOC disputes (together with a JOC member of the other Party) that have been unresolved for thirty (30) days to the JSC pursuant to Section 3.7. The JOC chairperson shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JOC members of the JOC.

(c) Meetings of the JOC. The chairperson of the JOC shall call meetings when deemed by the chairperson to be appropriate or when requested by a Party; provided, however, that such meetings shall be held on at least a quarterly basis for the first year following the Effective Date, and thereafter no less frequently than twice per year. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the companies) or where appropriate, by video or telephone conference. The Parties shall determine the form of the meeting. Decisions of the JOC shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided that no such vote shall be valid unless each Party is represented by at least one member either by proxy or actual presence at the meeting at which the vote is taken. Voting by proxy shall be permissible. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member to attend meetings where appropriate (e.g., representatives of regulatory affairs or outside consultants). Such additional participants shall not be deemed to be a member of the JOC, or to have any rights or responsibilities of a member of the JOC.

3.5 JOC Responsibilities. The responsibilities of the JOC shall also include, but shall not be limited to:

(a) making recommendations to the JSC with respect to target profiles for IL-1 Products (including key labeling claims required for commercial success of IL-1 Products given the competitive environment and any other key IL-1 Product features and benefits that would be used to develop or support a promotional message for IL-1 Products);

-23

(b) preparing, or overseeing the preparation of, Strategic Plans TL-1 Products for the Co-Commercialization Countries for final approval by the JSC, and updating each such Plan not less frequently than once per Contract Year;

(c) preparing, or overseeing the preparation of, Consolidated Co-Commercialization Plans (and related Consolidated Co-Commercialization Budgets) for the Co-Commercialization Countries in accordance with applicable Strategic Plans for final approval by the JSC, and updating each such Plan not less frequently than once per Contract Year;

(d) preparing, or overseeing the preparation of, Consolidated Co-Development Plans (and related Consolidated Co-Development Budgets) for the Co-Commercialization Countries in accordance with applicable Strategic Plans for final approval by the JSC, and updating each such Plan not less frequently than once per Contract Year;

(e) monitoring compliance with the Consolidated Co-Commercialization Plans and the Consolidated Co-Development Plans and, in connection therewith, reviewing and approving any material change in a Consolidated Co-Commercialization Plan or Consolidated Co-Development Plan, including, without limitation, specifically approving any change(s) in any line item or category of expenses in any Consolidated Co-Commercialization Budget or Consolidated Co-Development Budget which individually, or together with such previously approved changes in such line item or category, would result in a greater than five percent (5%) increase or decrease in the amount budgeted in such line item or category under either such Consolidated Co-Commercialization Budget or Consolidated Co-Development Budget, it being understood and agreed that expenditures by the Parties with respect to any matter included in a Consolidated Co-Commercialization Budget or Consolidated Co-Development Budget which individually or together with such prior expenditures, exceed by less than 5% the amount budgeted in any line item or category of expenses in such Consolidated Co-Commercialization Budget or Consolidated Co-Development Budget with respect to such matter shall not require approval by the JOC and for all purposes of this Agreement shall be deemed an expenditure in accordance with such Consolidated Co-Commercialization Budget or Consolidated Co-Development Budget, as applicable.

(f) approving protocols for Clinical Trials of IL-1
 Products in the applicable Territory, and monitoring and making modifications to such Clinical Trials;

(g) reviewing and approving material regulatory correspondence, final study reports and submissions to Regulatory Authorities with respect to IL-1 Products;

 (h) facilitating an exchange between the Parties of data, information, material and results relating to the Development of IL-1 Products in the applicable Territory;

 establishing and implementing procedures regarding the collection, sharing and reporting of adverse event information related to IL-1 Products in each country in the applicable Territory;

 $\rm (j)$  preparing and maintaining the overall plan for Commercialization of IL-1 Products in the Co-Commercialization Countries, defining joint planning and executing items, including, without limitation, timelines, IL-1 Product branding, positioning, core

-24-

messages, tactical plans, staffing, Detailing, Alternate Marketing Channels, budgets and amendments thereto;

 defining target groups to be covered by overall marketing efforts in the Co-Commercialization Countries, including, without limitation, key opinion leaders, physician groups, hospitals and regional buying groups, managed care organizations and governmental and government-affiliate buyers;

 reviewing the Parties' respective marketing and promotional activities for consistency with the Consolidated
 Co-Commercialization Plan;

(m) considering and selecting Product Trademarks for IL-1 Products for approval by the JSC;

 establishing the contents, design and layout of packaging for each IL-1 Product, on a country-by-country basis where applicable;

 developing and implementing plans and policies regarding journal and other publications with respect to IL-1 Products;

 $(p) \qquad \mbox{developing concepts for potential Phase IIIB and Phase IV Clinical Trials for IL-1 Products;}$ 

(q) establishing as sub-committees of the JOC (collectively, the "Joint Sub-Committees"), a U.S. Joint Commercialization Sub-Committee, a Finance Sub-Committee and an Intellectual Property Sub-Committee, each of which: (i) shall be composed of an equal number of representatives of each Party, with the right to appoint the chairperson rotating between the Parties, and otherwise organized in such a manner as the JOC deems appropriate; (ii) shall be delegated such responsibilities as the JOC deems appropriate; and (iii) shall report to the JOC;

(r) establishing, as and when necessary and/or appropriate, additional Joint Sub-Committees of the JOC such as a Joint Development Sub-Committee, a Joint Regulatory Sub-Committee, a Joint Commercialization Sub-Committee and/or Joint Country Commercialization Sub-Committees, which additional Joint Sub-Committees: (i) shall be composed of an equal number of representatives of each Party, with the right to appoint the chairperson rotating between the Parties, and otherwise organized in such a manner as the JOC deems appropriate; (ii) shall be delegated such responsibilities as the JOC deems appropriate; and (iii) shall report to the JOC; and

(s) considering and acting upon such other matters as are specified in this Agreement or by the Joint Steering Committee.

-25-

3.6 Alliance Management Representative. Each of Novartis and Regeneron 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"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among the Committees. Each Alliance Manager will also be responsible for:

 coordinating the various functional representatives of Novartis or Regeneron, as appropriate, in developing and executing global strategies and Plans for the IL-1 Product in an effort to ensure global consistency and efficiency;

(b) providing single-point communication for seeking consensus both internally within the respective Party's organization and together regarding key global 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 JSC in a timely manner.

3.7 Resolution of Governance Matters.

(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, and

 (i) In the case of any matter which cannot be resolved by the applicable Joint Sub-Committee of the JOC, such matter shall, at the request of either Party, promptly, and in any event within fifteen (15) days after such request, be referred by the chairperson of such Sub-Committee to the JOC for resolution;

(ii) in the case of any matter which cannot be resolved by the JOC, such matter shall, at the request of either Party, promptly, and in any event within thirty (30) days after such request, be referred by the chairperson of the JOC to the JSC for resolution; and

(iii) in the event any matter which cannot be resolved by the JSC, such matter shall, at the request of either Party, be resolved in accordance with the dispute resolution procedures set forth in Section 3.7(b) and (c) below.

-26-

Any such final decision [\*\*\*\*\*\*\*\*\*\*\*\*\*] shall be made, and communicated in writing [\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*]. For the avoidance of doubt, such disputes referred to the Executive Officers for resolution (other than Legal Disputes) shall not be subject to any dispute resolution mechanism or procedure other than pursuant to this Article III.

(i)	[**************************************
(ii)	[**************************************
(iii)	[**************************************
(iv)	[*************************************
(v)	[**************************************

(d) Performance. Pending resolution of any matter pursuant to this Section 3.7, the Parties covenant to continue their performance under the Agreement in accordance with the terms thereof. To facilitate such continued performance, pending resolution by the Executive Officers of any referred dispute with respect to an annual Consolidated Co-Commercialization Budget or annual Consolidated Co-Development Budget, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets to allow the continued Co-Development and Co-Commercialization of the IL-1 Product pursuant to this Agreement.

(e) Obligations of the Parties and their Affiliates. 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 Executives in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder for any failure of such performance, and each Party agrees that it will cause each of its controlled Affiliates to comply with any provision of this Agreement which restricts or prohibits a Party from taking any specified action.

# ARTICLE IV

## EXISTING PATENT AND KNOW-HOW RIGHTS; LICENSE GRANTS

4.1 Regeneron License Grants Regarding Trap-1. Subject to the terms and conditions of this Agreement and any license within the Regeneron Patent Rights, Regeneron hereby grants to Novartis and its Affiliates the right and license under the Regeneron Intellectual Property to manufacture, and to Co-Develop, Co-Commercialize and Co-Market the Trap-1 Product throughout the Trap-1 Territory for the Term of this Agreement. Such license shall be co-exclusive with Regeneron and its Affiliates only. The rights granted to Novartis and its Affiliates under the Regeneron Intellectual Property to sell or offer to sell the Trap-1 Product shall be sublicensable to Distributors of Novartis (but not with respect to distribution, marketing, sale or offer for sale of the Trap-1 Product in any country listed on SCHEDULE 10), and otherwise only with the prior written consent of Regeneron, which

-27-

consent shall not be unreasonably withheld or delayed. For the avoidance of doubt, Regeneron may withhold such consent if it reasonably determines such sublicense would reduce Regeneron's financial return from the sale of the Trap-1 Product in the applicable country.

4.2 Novartis License Grants Regarding the IL-1 Antibody. Subject to the terms and conditions of this Agreement and any license within the Novartis Patent Rights, Novartis and its Affiliates hereby grant to Regeneron and its Affiliates the right and license under the Novartis Intellectual Property to Co-Develop, Co-Commercialize and Co-Market the IL-1 Antibody Product throughout the IL-1 Antibody Territory for the Term of this Agreement with respect to the IL-1 Antibody Product. Such license shall be conditional upon the proper exercise by Regeneron of the IL-1 Antibody Opt-In Right and shall be co-exclusive with Novartis and its Affiliates only. The rights granted to Regeneron and its Affiliates hereunder shall not be sublicensable.

4.3 Regeneron License Grants Regarding Trap-2. Subject to the terms and conditions of this Agreement and any license within the Regeneron Patent Rights, Regeneron hereby grants to Novartis and its Affiliates the right and license under the Regeneron Intellectual Property to manufacture, and to Co-Develop, Co-Commercialize and Co-Market the Trap-2 Product throughout the Trap-2 Territory for the Term of this Agreement with respect to the Trap-2 Product. Such license shall be conditional upon the proper exercise by Novartis of the Trap-2 Opt-In Right and shall be co-exclusive with Regeneron and its Affiliates only. The rights granted to Novartis and its Affiliates under the Regeneron Intellectual Property to sell or offer to sell the Trap-2 Product shall be sublicensable to Distributors of Novartis (but not with respect to distribution, marketing, sale or offer for sale of the Trap-2 Product in any country listed on SCHEDULE 10), and otherwise only with the prior written consent of Regeneron, which consent shall not be unreasonably withheld or delayed. For the avoidance of doubt, Regeneron may withhold such consent if it reasonably determines such sublicense would reduce Regeneron's financial return from the sale of the Trap-2 Product in the applicable country.

4.4 Technology Transfer.

(a) To the extent reasonably necessary for each Party to exercise its rights and perform its obligations under this Agreement with respect to the other Party's intellectual property, and from time to time during the applicable Term, each Party shall provide to the other Party one (1) copy of each physical embodiment of such Party's applicable intellectual property as set forth in the Technology Transfer Agreement. Without limiting the generality of any other provision of this Agreement or the Technology Transfer Agreement, each Party shall make its scientific and technical personnel available to the other Party to answer any questions or provide instruction as reasonably necessary with respect to such Party's intellectual property licensed to the other Party hereunder.

(b) In accordance with the terms of a Technology Transfer Agreement (to be negotiated in good faith as soon as practicable, but in any event within sixty (60) days of the Effective Date), Regeneron will transfer and license to Novartis such Know-How and Regeneron Intellectual Property on terms to be set forth in the Technology Transfer Agreement to allow Novartis to assume the manufacturing of the Trap-1 Product. The Parties agree to enter into a similar technology transfer agreement, as needed, for the Trap-2 Product.

-28-

4.5 Sublicenses. Novartis shall remain responsible for the compliance by its Distributors and permitted sublicensees with applicable terms and obligations set forth herein. Novartis agrees that any sublicense granted pursuant to Section 4.1 or 4.3 shall be consistent with, and expressly subject to, the covenants, terms and conditions set forth in this Agreement. Without limitation of the generality of the foregoing, any sublicense granted pursuant to Section 4.1 or 4.3 shall contain all of the terms required by the Amgen License Agreement to be included in a sublicense of any rights licensed to Regeneron thereunder, including, without limitation, that Amgen Inc. shall be a direct third party beneficiary of any such sublicense. Promptly after entering into any such sublicense, or any amendment or modification thereto, Novartis will provide a true and correct copy thereof to Regeneron.

# ARTICLE V

# DEVELOPMENT AND OPT-IN RIGHTS

# 5.1 Pre-Phase III Development of the IL-1 Antibody.

(b) Novartis shall keep Regeneron and the JSC informed of Novartis' Development activities with respect to the IL-1 Antibody Product through the End of Phase II Development of the IL-1 Antibody Product by submitting to the JSC, annually on each anniversary of the Effective Date, a development plan with respect to the future Development of the IL-1 Antibody Product and a progress report summarizing all Development activities undertaken with respect to the IL-1 Antibody Product in the preceding year and which shall include all relevant data from such Development activities. Each such development plan and progress report shall be in such form and in such level of detail as may be reasonably requested by Regeneron.

(c) Novartis shall also provide Regeneron and the JSC with reasonable advance notice of any meetings between Novartis and any Regulatory Authority relating to the Development of any IL-1 Antibody Product prior to the End of Phase II Development. To the extent permitted under Law, Novartis shall permit Regeneron to have representatives attend any such regulatory meeting with respect to the Development of any IL-1 Antibody Product prior to the End of Phase II Development.

5.2 Pre-Phase III Development of Trap-2.

(a) Regeneron shall be solely responsible, in its sole discretion, for the Development of the Trap-2 Product through the End of Phase II Development and for all associated Development costs and expenses.

(b) Regeneron shall keep Novartis and the JSC informed of Regeneron's Development activities with respect to the Trap-2 Product through the End of Phase II Development of the Trap-2 Product by submitting to the JSC, annually on each anniversary

-29-

of the Effective Date, a development plan with respect to the future Development of the Trap-2 Product and a progress report summarizing all Development activities undertaken with respect to the Trap-2 Product in the preceding year and which shall include all relevant data from such Development activities. Each such development plan and progress report shall be in such form and in such level of detail as may be reasonably requested by Novartis.

(c) Regeneron shall also provide Novartis and the JSC with reasonable advance notice of any meetings between Regeneron and any Regulatory Authority relating to the Development of any Trap-2 Product prior to the End of Phase II Development. To the extent permitted under Law, Regeneron shall permit Novartis to have representatives attend any such regulatory meeting with respect to Development of any Trap-2 Product prior to the End of Phase II Development.

### 5.3 IL-1 Antibody Opt-In Rights.

(a) Novartis hereby grants to Regeneron an exclusive option to Co-Develop and Co-Commercialize with Novartis and its Affiliates the IL-1 Antibody Product on the terms and conditions set forth in this Agreement.

Within forty-five (45) days after the End of Phase II (b) Development of the IL-1 Antibody Product, Novartis shall deliver to Regeneron written notice of the End of Phase II Development, accompanied by a written report setting forth such efficacy, safety, clinical and medical data as may be material to the feasibility of further Developing and Commercializing the  $\ensuremath{\operatorname{IL-1}}$ Antibody Product, which shall include, without limitation, a proposed development plan and budget and a summary of the data generated from the pre-clinical and clinical studies in sufficient detail so as to reasonably demonstrate that efficacy has been achieved in accordance with defined endpoints and whether any unexpected or untoward effects resulted from such studies which would limit further Development of the IL-1 Antibody Product. For a period of thirty (30) days from and after the delivery of such notice and reports, Regeneron shall have the right to request from Novartis such additional information then in the possession of or readily available to Novartis as Regeneron may reasonably require in order to make a scientific, legal and business evaluation of the Development and marketing potential of the IL-1 Antibody Product. Novartis shall also promptly notify Regeneron of, and promptly provide to Regeneron, all material new data relating to the IL-1 Antibody Product that comes into Novartis' possession during such period, whether or not such data is specifically requested by Regeneron.

(c) For ninety (90) days after the date of delivery of the notice and written report described in Section 5.3(b) above or, if later, the date Regeneron has received the additional information requested by Regeneron in accordance with Section 5.3(b), Regeneron shall have the right to elect to Co-Develop and Co-Commercialize the IL-1 Antibody Product on the terms and conditions set forth in this Agreement. Any exercise of the IL-1 Antibody Opt-In Right shall be made by written notice to Novartis, accompanied by the IL-1 Antibody Opt-In Payment and shall become effective at the end of the month during which such notice was delivered to Novartis. Development Costs with respect to the IL-1 Antibody Product incurred after the effective date of such notice shall be shared by the Parties in accordance with Schedule 4. If Regeneron fails to exercise its IL-1 Antibody Opt-In Right as set forth above, the IL-1 Antibody shall not be included in the Co-Development, manufacture, Co-Commercialization or Co-Marketing of IL-1 Products as contemplated by this Agreement, this Agreement (including, without limitation, Sections 2.1, 2.4(c), 4.2, 4.4, 5.1, 5.3, 5.5, 6.1, 8.3, 13.3 and 15.2(b) and Articles III, VII and XI) shall be of no force or effect with respect

-30-

to the IL-1 Antibody, and Novartis and its Affiliates shall be free to Develop and Commercialize the IL-1 Antibody Product, alone or in collaboration with any Third Party, without being subject to the provisions of this Agreement (including, without limitation, Section 6.22).

#### 5.4 Trap-2 Opt-In Right.

(a) Regeneron hereby grants to Novartis an exclusive option to Co-Develop and Co-Commercialize with Regeneron the Trap-2 Product on the terms and conditions set forth in this Agreement.

(b) Within forty-five (45) days after the End of Phase II Development of the Trap-2 Product, Regeneron shall deliver to Novartis written notice of the End of Phase II Development, accompanied by a written report setting forth such efficacy, safety, clinical and medical data as may be material to the feasibility of further Developing and Commercializing the Trap-2 Product, which shall include, without limitation, manufacturing data, a proposed development plan and budget and a summary of the data generated from the pre-clinical and clinical studies in sufficient detail so as to reasonably demonstrate that efficacy has been achieved in accordance with defined endpoints and whether any unexpected or untoward effects resulted from such studies which would limit further Development of the Trap-2 Product. For a period of thirty (30) days from and after the delivery of such notice and reports, Novartis shall have the right to request from Regeneron such additional information then in the possession of or readily available to Regeneron as Novartis may reasonably require in order to make a scientific, legal and business evaluation of the Development and marketing potential of the Trap-2 Product. Regeneron shall also promptly notify Novartis of, and promptly provide to Novartis, all material new data relating to the Trap-2 Product that comes into Regeneron's possession during such period, whether or not such data is specifically requested by Novartis.

(c) For ninety (90) days after the date of delivery of the notice and written report described in Section 5.4 (b) above or, if later, the date Novartis has received the additional information requested by Novartis in accordance with Section 5.4 (b), Novartis shall have the right to elect to Co-Develop and Co-Commercialize the Trap-2 Product on the terms and conditions set forth in this Agreement. Any exercise of the Trap-2 Opt-In Right shall be made by written notice to Regeneron and shall become effective at the end of the month during which such notice was delivered to Regeneron. Development Costs with respect to the Trap-2 Product incurred after the effective date of such notice shall be shared by the Parties in accordance with Schedule 4. If Novartis fails to exercise its Trap-2 Opt-In Right as set forth above, the Trap-2 Product shall not be included in the Co-Development, manufacture, Co-Commercialization or Co-Marketing of IL-1 Products as contemplated by this Agreement, this Agreement (including, without limitation, Sections 2.1, 2.4(c), 4.3, 4.4, 5.2, 5.4, 5.5, 6.1, 8.4, 13.3 and 15.2(a) and Articles III, VII and XI ) shall be of no force or effect with respect to the Trap-2 Product, and Regeneron shall be free to Develop and Commercialize the Trap-2 Product, alone or in collaboration with any Third Party, without being subject to the provisions of this Agreement (including, without limitation, Section 6.22).

5.5 Grant of Co-Development Rights.

(a) Subject to the terms of this Agreement and any Ancillary Agreement (including, without limitation, the exercise of the applicable IL-1 Antibody Opt-In Rights and

-31-

the Trap-2 Opt-In Rights, the exceptions set forth in Section 6.2 and the rights retained by the respective Parties hereunder in connection with IL-1 Products) and subject to the terms of any license within any applicable Patent Rights, each Party grants to the other Party and its Affiliates the sole right, together with the granting Party and its Affiliates, to Co-Develop IL-1 Products in the applicable Territory and for the applicable Term with respect to each IL-1 Product. For so long as a Party's rights of Co-Development under this Section 5.5(a) remain in effect with respect to a particular country with respect to a particular IL-1 Product, the granting Party shall not grant any rights to, or permit or authorize, any Third Party to Develop such IL-1 Product in such country; provided that the foregoing shall not in any manner limit (a) the granting Party's (or its Affiliates') activities in the Co-Development of applicable IL-1 Product(s) as contemplated under this Agreement, or (b) the granting Party's (or its Affiliates') Development activities with respect to applicable IL-1 Product(s) outside of the applicable Territory.

(b) The rights granted to Regeneron and its Affiliates under Section 5.5(a) shall not be sublicensable. The rights granted to Novartis and its Affiliates under Section 5.5(a) shall be sublicensable only with the prior written consent of Regeneron, which consent shall not be unreasonably withheld or delayed.

-32-

5.6 Co-Development of IL-1 Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to the Trap-1 Product and any other IL-1 Product under the direction and oversight of the Committees and in accordance with all applicable Consolidated Co-Development Plans. Each Party shall use Commercially Reasonable Efforts to carry out the Development activities assigned to it in such Consolidated Co-Development Plans and to conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices and export and import control Laws. In carrying out Development activities hereunder with respect to IL-1 Products, neither Party shall use the services of any Person involved in the Development of any Trap-1 Product, IL-1 Antibody Product (following the End of Phase II Development) or Trap-2 Product (following the End of Phase II Development) which is not an IL-1 Product subject to the Co-Development and/or Co-Commercialization rights pursuant to this Agreement, if the use of such services would violate applicable Law.

5.7 Co-Development Plans. Subject to the terms of Article III above and the applicable Ancillary Agreements, the JOC shall annually develop Consolidated Co-Development Plans for IL-1 Products, for approval by the JSC. Each Consolidated Co-Development Plan shall incorporate a Consolidated Co-Development Budget and will set forth the plan for Development of each applicable IL-1 Product on a calendar-year basis, including, without limitation: (a) strategies for Developing and obtaining Approvals for such IL-1 Product; and (b) allocation of responsibilities for Development activities between the Parties, and/or to Third Party service providers to the extent permitted by the applicable Consolidated Development Plan. Until such time as the Clinical Trials and other activities described or referred to in the Preliminary Development Plan attached hereto as SCHEDULE 8 (the "Preliminary Development Plan") have been completed (unless the Preliminary Development Plan as been amended or modified by the JSC in compliance with Article III (including Section 3.7(c)), each Consolidated Co-Development Plan shall be consistent with the Preliminary Development Plan and designed to complete as expeditiously as is commercially reasonable such Clinical Trials and other activities described or referred to in the Preliminary Development Plan.

5.8 Co-Development Reports. Within thirty (30) days after the end of each quarter, Regeneron and Novartis shall each provide to the other Party and to the JOC a written report (in electronic form) summarizing in reasonable detail the material activities undertaken by such Party during such quarter in connection with each Consolidated Co-Development Plan, together with a detailed project-level statement of Development Costs incurred by such Party during such quarter.

5.9 Loan Facilities for Trap-1 Product Development Costs.

(a) 2003 Development Costs Facility.

(i) General. Novartis shall create an internal loan facility from which, subject to the further provisions hereof, it shall make advances to Regeneron, and from which Regeneron may draw funds in U.S. Dollars from time to time, in amounts that in the aggregate equal up to the share of Development Costs incurred in 2003 in connection with the Co-Development of Trap-1 Products for which Regeneron is responsible in accordance with SCHEDULE 4 of the Agreement (the "2003 Regeneron Development Costs"). Such loan facility is referred to herein as the "2003 Facility", and such advances made thereunder are referred to herein collectively as the "2003 Facility Loans".

-33-

(ii) Draws. To draw on the 2003 Facility, Regeneron shall submit a notice of funding (a "2003 Facility Funding Notice") to Novartis, signed by its Chief Financial Officer, specifying the amount of the requested advance (which shall not be less than \$1 million per request) and certifying that such amount is in respect of 2003 Regeneron Development Costs. 2003 Facility Loans shall be made by Novartis within twenty (20) Business Days after Novartis' receipt of a 2003 Facility Funding Notice.

(iii) Crediting of 2003 Facility Loans; Cash Disbursements. Immediately upon any 2003 Facility Loan being made, Regeneron hereby authorizes and directs Novartis to, and Novartis shall, credit the amount of such 2003 Facility Loan against 2003 Regeneron Development Costs, and each of Regeneron and Novartis acknowledges and agrees that there will be no cash disbursements of any 2003 Facility Loans to the extent they are so applied against 2003 Regeneron Development Costs; provided, however, that Novartis shall disburse to Regeneron (as Regeneron may direct Novartis in a 2003 Facility Funding Notice) all or a portion of any 2003 Facility Loan to the extent of 2003 Regeneron Development Costs actually incurred by Regeneron or its Affiliates. Any cash disbursement of a 2003 Facility Loan shall be made by Novartis by wire transfer of funds to an account specified by Regeneron in the 2003 Facility Funding Notice within the time period provided in subparagraph (ii) above.

(iv) Interest. The principal balance of 2003 Facility Loans outstanding shall bear interest from the date advanced at a rate per annum equal to the LIBOR Rate, plus 2.5%, and shall be compounded quarterly and, unless the 2003 Facility Loans have been accelerated in accordance with subparagraph (x) below, shall be payable as provided in subparagraph (v) below. For purposes of this Section 5.9 and Section 6.23, "LIBOR Rate" shall mean the rate for three (3) months LIBOR (such period, with respect to any 2003 Facility Loan, any Post-2003 Facility Loan or any Promotional Expenses Facility Loan, the "LIBOR Period") for U.S. Dollars as reported by Datastream. Overdue principal and, to the extent permitted by law, overdue interest in respect of each 2003 Facility Loan shall, in each case, bear interest at a rate per annum equal to the rate which is 2% in excess of the rate borne by such 2003 Facility Loan. Interest which accrues under the immediately preceding sentence shall be payable on demand.

(vi) Prepayment. Regeneron shall have the right to prepay any 2003 Facility Loans prior to the time required in subparagraph (v) above, without premium or penalty (except as provided below in subparagraph (viii)), in whole or in part, upon at least one Business Day's prior written notice (or telephonic notice confirmed by in writing, which may be by email) to Novartis of its intent to make such prepayment. The amount of any such prepayment (or repayment, whether pursuant to clause (v), (x) or (xi)) shall be applied pro rata against the principal amount of the then outstanding 2003 Facility Loans and accrued and unpaid interest thereon, in the order

-34-

of their dates of disbursement, with any prepayment being first applied against the longest outstanding 2003 Facility Loan.

(vii) Method of Repayment. Except as otherwise specifically provided herein, all payments of principal of, and accrued interest on, 2003 Facility Loans shall be made in U.S. Dollars in immediately available funds to an account of Novartis specified by it to Regeneron, and shall be paid net of withholding taxes, if applicable.

(viii) Breakage Cost. Regeneron shall compensate Novartis, upon the written request of Novartis, for any expenses or costs (a reasonably detailed calculation of which shall be provided by Novartis together with such written request) incurred by Novartis as a result of any prepayment pursuant to clause (vi) of any one or more 2003 Facility Loans having occurred on a date other than the last date of a LIBOR Period relating to such 2003 Facility Loan or 2003 Facility Loans.

(ix) Termination of 2003 Facility. The 2003 Facility shall automatically terminate, and no further 2003 Facility Loans shall be advanced thereunder, upon the earlier of (A) the effective date of termination of the Agreement by Novartis with respect to the entire Trap-1 Territory for all Trap-1 Products and (B) the acceleration of the date of payment of 2003 Facility Loans pursuant to subparagraph (x) below.

 $(\mathbf{x})$   $\quad$  Acceleration of 2003 Facility Loans. Novartis may, by notice to Regeneron, declare all principal of, and accrued and unpaid interest on, all 2003 Facility Loans due and payable, if a 2003 Facility Loan Event of Default referred to in clause (A) or (B) below in this subparagraph (x) shall have occurred (and in such event upon such notice all such principal and unpaid interest shall immediately become due and payable) or if a 2003 Facility Loan Event of Default referred to in clause (C) below in this subparagraph (x) shall have occurred (and in such event upon such notice all such principal and interest shall be due and payable upon the first anniversary of the date of such notice), and if a 2003 Facility Loan Event of Default referred to in clause (D) of such definition shall have occurred, all such principal and interest shall automatically become due and payable. The occurrence of any of the following events shall constitute a "2003 The occurrence of any of the following events shall constitute a Facility Loan Event of Default": (A) Regeneron shall default in the payment when due of the principal of, and accrued and unpaid interest on, the 2003 Facility Loans, (B) the due date of indebtedness for borrowed money of Regeneron in an amount exceeding \$10 million shall have been accelerated and Regeneron shall have failed to make payment thereof in full on the accelerated payment date, (C) the Agreement to and in accordance with Section 19.5 of the Agreement and such termination shall be effective or (D) Regeneron shall commence a voluntary case concerning itself under the Bankruptcy Code, or an involuntary case under the Bankruptcy Code shall be commenced against Regeneron and the petition is not controverted within 10 days, or is not dismissed within 60 days, after commencement of the case, or a custodian (as defined in the Bankruptcy Code) is appointed for, or takes charge of, all or substantially all of the property of Regeneron, or Regeneron commences any other proceeding under any reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction whether now or hereafter in effect relating to Regeneron or there is commenced against Regeneron any such proceeding which remains undismissed for a period of 60 days, or Regeneron is adjudicated insolvent or bankrupt, or any order of relief or other order approving any such case or

-35-

proceeding is entered, or Regeneron suffers any appointment of any custodian or the like for it or any substantial part of its property to continue undischarged or unstayed for a period of 60 days, or Regeneron makes a general assignment for the benefit of creditors, or any corporate action is taken by Regeneron for the purpose of effecting any of the foregoing.

(xi) Right of Set-off. In addition to any rights now or hereafter granted under applicable law or otherwise, and not by way of limitation of any such rights, if any default by Regeneron in repaying when due all principal of, and accrued and unpaid interest on, all outstanding 2003 Facility Loans has occurred and is continuing, Novartis may, upon prior notice to Regeneron, set off against all such unpaid principal and interest any amount payable by Novartis to Regeneron under this Agreement.

#### (b) Post-2003 Development Costs Facility.

(i) General. Novartis shall create an internal loan facility from which, subject to the further provisions hereof, it shall make advances to Regeneron, and from which Regeneron may draw funds in U.S. Dollars from time to time, in amounts that in the aggregate equal up to the share of Development Costs incurred after 2003 in connection with the Co-Development of Trap-1 Products for which Regeneron is responsible in accordance with SCHEDULE 4 of the Agreement (the "Post-2003 Regeneron Development Costs"). Such loan facility is referred to herein as the "Post-2003 Facility", and such advances made thereunder are referred to herein collectively as the "Post-2003 Facility Loans".

(ii) Draws. To draw on the Post-2003 Facility, Regeneron shall submit a notice of funding (a "Post-2003 Facility Funding Notice") to Novartis, signed by its Chief Financial Officer, specifying the amount of the requested advance (which shall not be less than \$1 million per request) and certifying that such amount is in respect of Post-2003 Regeneron Development Costs. Post-2003 Facility Loans shall be made by Novartis within twenty (20) Business Days after Novartis' receipt of a Post-2003 Facility Funding Notice.

(iii) Crediting of Post-2003 Facility Loans; Cash Disbursements. Immediately upon any Post-2003 Facility Loan being made, Regeneron hereby authorizes and directs Novartis to, and Novartis shall, credit the amount of such Post-2003 Facility Loan against Post-2003 Regeneron Development Costs, and each of Regeneron and Novartis acknowledges and agrees that there will be no cash disbursements of any Post-2003 Facility Loans to the extent they are so applied against Post-2003 Regeneron Development Costs, provided, however, that Novartis shall disburse to Regeneron (as Regeneron may direct Novartis in a Post-2003 Facility Funding Notice) all or a portion of any Post-2003 Facility Loan to the extent of Post-2003 Regeneron Development Costs actually incurred by Regeneron or its Affiliates. Any cash disbursement of a Post-2003 Facility Loan shall be made by Novartis by wire transfer of funds to an account specified by Regeneron in the Post-2003 Facility Funding Notice within the time period provided in subparagraph (ii) above.

(iv) Interest. The principal balance of Post-2003 Facility Loans outstanding shall bear interest from the date advanced at a rate per annum equal to the LIBOR Rate, plus 2.5%, and shall be compounded quarterly and, unless the Post-2003

-36-

Facility Loans have been accelerated in accordance with subparagraph (x) below, shall be payable as provided in subparagraph (v) below. Overdue principal and, to the extent permitted by law, overdue interest in respect of each Post-2003 Facility Loan shall, in each case, bear interest at a rate per annum equal to the rate which is 2% in excess of the rate borne by such Post-2003 Facility Loan. Interest which accrues under the immediately preceding sentence shall be payable on demand.

(v) Repayment. The full amount of all outstanding Post-2003 Facility Loans, and all accrued and unpaid interest thereon, will be due and payable five (5) years after the earlier of (A) the first Launch of a Trap-1 Product in the United States or Europe and (B) the effective date of termination of the Agreement by Novartis with respect to the entire Trap-1 Territory for all Trap-1 Products.

(vi) Prepayment. Regeneron shall have the right to prepay any Post-2003 Facility Loans prior to the time required in subparagraph (v) above, without premium or penalty (except as provided below in subparagraph (viii)), in whole or in part, upon at least one Business Day's prior written notice (or telephonic notice confirmed by in writing, which may be by email) to Novartis of its intent to make such prepayment. The amount of any such prepayment (or repayment, whether pursuant to clause (v), (x) or (xi)) shall be applied pro rata against the principal amount of the then outstanding Post-2003 Facility Loans and accrued and unpaid interest thereon, in the order of their dates of disbursement, with any prepayment being first applied against the longest outstanding Post-2003 Facility Loan.

(vii) Method of Repayment. Except as otherwise specifically provided herein, all payments of principal or accrued interest on Post-2003 Facility Loans shall be made in U.S. Dollars in immediately available funds to an account of Novartis specified by it to Regeneron, and shall be paid net of withholding taxes, if applicable.

(viii) Breakage Cost. Regeneron shall compensate Novartis, upon the written request of Novartis, for any expenses or costs (a reasonably detailed calculation of which shall be provided by Novartis together with such written request) incurred by Novartis as a result of any prepayment pursuant to clause (vi) of any one or more Post-2003 Facility Loans having occurred on a date other than the last date of a LIBOR Period relating to such Post-2003 Facility Loan or Post-2003 Facility Loans.

(ix) Termination of Post-2003 Facility. The Post-2003 Facility shall automatically terminate, and no further Post-2003 Facility Loans shall be advanced thereunder, upon the early of (A) the effective date of termination of the Agreement by Novartis with respect to the entire Trap-1 Territory for all Trap-1 Products and (B) the acceleration of the date of payment of Post-2003 Facility Loans pursuant to subparagraph (x) below.

(x) Acceleration of Post-2003 Facility Loans. Novartis may, by notice to Regeneron, declare all principal of, and accrued and unpaid interest on, all Post-2003 Facility Loans due and payable, if a Post-2003/Promotional Expense Event of Default referred to in clause (A) or (B) below in this subparagraph (x) shall have occurred (and in such event upon such notice all such principal and unpaid interest shall immediately become due and payable) or if a Post-2003/Promotional Expense Event of Default referred to in clause (C) below in this subparagraph (x) shall have occurred (and in such event upon such notice all such principal and interest shall be due and

-37-

payable upon the first anniversary of the date of such notice), and if a Post-2003/Promotional Expense Event of Default referred to in clause (D) of such definition shall have occurred, all such principal and interest shall automatically become due and payable. The occurrence of any of the following events shall constitute an "Post-2003/Promotional Expense Event of Default": (A) Regeneron shall default in the payment Expense Event of Default": (A) Regeneron shall default in the payment when due of all principal of, and accrued and unpaid interest on, the Promotional Expense Facility Loans or the Post-2003 Facility Loans, (B) the due date of indebtedness for borrowed money of Regeneron in an amount exceeding \$10 million shall have been accelerated and Regeneron shall have failed to make payment thereof in full on the accelerated payment date, (C) the Agreement shall have been validly terminated in its entirety by Novartis pursuant to and in accordance with Section 19.5 of the Agreement and such termination shall be effective or (D) Regeneron shall commence a voluntary case concerning itself under the Bankruptcy Code or an involuntary case under the Bankruptcy Code shall be commenced against Regeneron and the petition is not controverted within 10 days, or is not dismissed within 60 days, after commencement of the case, or a custodian (as defined in the Bankruptcy Code) is appointed for, or takes charge of, all or substantially all of the property of Regeneron, or Regeneron commences any other proceeding under any reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction whether now or hereafter in effect relating to Regeneron or there is commenced against Regeneron any such proceeding which remains undismissed for a period of 60 days, or Regeneron is adjudicated insolvent or bankrupt, or any order of relief or other order approving any such case or proceeding is entered, or Regeneron suffers any appointment of any custodian or the like for it or any substantial part of its property to continue undischarged or unstayed for a period of 60 days, or Regeneron makes a general assignment for the benefit of creditors, or any corporate action is taken by Regeneron for the purpose of effecting any of the foregoing.

(xi) Right of Set-off. In addition to any rights now or hereafter granted under applicable law or otherwise, and not by way of limitation of any such rights, any default by Regeneron in repaying when due all principal of, and accrued and unpaid interest on, all outstanding Post-2003 Facility Loans has occurred and is continuing, Novartis may, upon prior notice to Regeneron, set off against all such unpaid principal and interest any amount payable by Novartis to Regeneron under the Agreement.

Survival. This Section 5.9 shall survive termination

(c) of this Agreement.

#### ARTICLE VI

#### CO-COMMERCIALIZATION

#### 6.1 Grant of Co-Commercialization Rights.

(a) Subject to the terms of this Agreement and any Ancillary Agreement (including, without limitation, the exercise of the IL-1 Antibody Opt-In Rights and the Trap-2 Opt-In Rights, as applicable, the exceptions set forth in Section 6.2 and the rights retained by the respective Parties hereunder in connection with IL-1 Products) and subject to the terms of any license within any applicable Patent Rights, each Party grants to the other Party and its Affiliates the sole right, together with the granting Party and its Affiliates, to Co-

-38-

Commercialize IL-1 Products in each of the Co-Commercialization Countries for the applicable Term in each such Co-Commercialization Country. For so long as a Party's rights of Co-Commercialization under this Section 6.1(a) remain in effect with respect to any Co-Commercialization Country, the granting Party shall not grant any rights to, or permit or authorize, any Third Party to Commercialize, promote or Detail any applicable IL-1 Product in such Co-Commercialization Country; provided that the foregoing shall not in any manner limit (a) the granting Party's (or its Affiliates') activities in the Co-Commercialization of applicable IL-1 Product(s) as contemplated under this Agreement, (b) the granting Party's (or its Affiliates') commercialization activities with respect to applicable IL-1 Product(s) outside of the applicable Territory, or (c) the granting Party's (or its Affiliates') right to permit or authorize any Third Party to serve as a Distributor for the applicable IL-1 Product.

(b) The rights granted to Regeneron and its Affiliates under Section 6.1(a) shall not be sublicensable. The rights granted to Novartis and its Affiliates under Section 6.1(a) shall be sublicensable to Distributors of Novartis (but not with respect to the Commercialization of IL-1 Products in any country listed on SCHEDULE 10) and otherwise only with the prior written consent of Regeneron, which consent shall not be unreasonably withheld or delayed. For the avoidance of doubt, Regeneron may withhold such consent if it reasonably determines such sublicense would reduce Regeneron's financial return from the sale of the applicable IL-1 Product in the applicable country.

(c) The provisions of Sections 6.4 to 6.20 inclusive (such provisions, the "Co-Commercialization Provisions") shall apply in each Co-Commercialization Country.

6.2 Exceptions to the Grant of Co-Commercialization Rights.

(a) The Parties may, from time to time, jointly agree, by unanimous affirmative vote of all members of the JSC, to exclude a Co-Commercialization Country from the applicable Territory.

(b) The Parties may, from time to time, mutually agree to designate certain Co-Commercialization Countries as Exclusive Countries for either Novartis or Regeneron. The commercial terms relating to marketing in such Exclusive Countries will be as the Parties may at the time mutually agree at such time.

(c) The Parties may, from time to time, mutually agree to exclude, by amendment of the applicable definition of "Territory" in accordance with Section 20.5, certain Co-Commercialization Countries from the applicable Territory; provided, however, that such countries may also be reinstated to the applicable Territory by amendment of the applicable definition of "Territory" in accordance with Section 20.5.

(d) No later than ninety (90) days prior to the date of Launch of an IL-1 Product in a Co-Commercialization Country, the Parties may agree, through the JSC, that it would be in the best interests of both Parties to Co-Market the IL-1 Product in such Co-Commercialization Country, in which case such Co-Commercialization Country shall be deemed forthwith to be a Co-Marketing Country and shall be subject to a separate Co-Marketing Agreement between the Parties.

 $\,$  6.3 Commercialization of IL-1 Products in Co-Marketing Countries. In the event (and for so long as) the Parties are not permitted under local Law to Co-Promote or Co-Brand IL-1 Products in any country in the applicable Territory, but are permitted to Co-

-39-

Market the IL-1 Products in such country (i.e., a "Co-Marketing Country"), then the Parties (in the case of Regeneron, directly, or through a Third-Party licensee) shall Co-Market the IL-1 Products in such Co-Marketing Country in accordance with a separate Co-Marketing Agreement to be agreed in good faith between the Parties and, to the extent not prohibited by applicable Law in such Co-Marketing Country in accordance with (a) the obligations set forth in the Co-Commercialization Provisions applicable to the Co-Commercialization Countries and (b) the other provisions of this Agreement. In the event any such provisions of this Agreement are prohibited by applicable Law in a Co-Marketing Country and are not covered by the Co-Marketing Agreement, then such provision shall be considered a Severed Clause under Section 20.7 solely with respect to such Co-Marketing Country. If prior to a Registration Filing in a Co-Marketing Country, or any mutually agreed upon time thereafter, Regeneron notifies Novartis that it does not intend to Co-Market the applicable IL-1 Product in such Co-Marketing Country, then Novartis shall have the exclusive right to Develop and Commercialize the IL-1 Product in such Co-Marketing Country; provided that for purposes of determining payment of Development Costs and determining the Target Profit Split, the Country shall be treated as a Co-Commercialization Country hereunder.

6.4 Commercialization of IL-1 Products in Co-Commercialization Countries. Novartis and Regeneron (through their respective Affiliates where appropriate) shall Co-Promote and Co-Brand IL-1 Products under the applicable Product Trademarks in each Co-Commercialization Country during the applicable Term in accordance with the then-current JSC-approved Consolidated Co-Commercialization Plan, Consolidated Co-Commercialization Budgets, Using substantially equivalent quality of efforts and resources. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts in performing such obligations. Notwithstanding any other provision of this Agreement, the Parties shall not be required to Launch any IL-1 Product in any Co-Commercialization Country unless and until: (a) full commercial channels of distribution have been established in the applicable country; and (b) IL-1 Product inventory sufficient to meet reasonably anticipated levels of demand has been procured, it being understood and agreed that, upon the terms and subject to the conditions of this Agreement, the Parties will use Commercially Reasonable Efforts to finally establish such distribution channels and procure such inventory so the Launch of such IL-Product will not be delayed.

 (a) strategies for the Detailing and Co-Promotion or Co-Branding, as applicable, of the IL-1 Products, including recommended target Professionals for such activities;

-40-

 (b) allocation between the Parties of responsibilities for marketing, sales and promotional activities (except that in the case of Detailing, such allocation shall be preliminary and shall be finally determined as provided in Section 6.10(a));

(c) anticipated marketing, sales and promotion efforts by each Party (or its Affiliates) (including number and position of Details, and sampling activities);

(d) market and sales forecasts in a form to be agreed between the Parties via the Joint Operating Committee;

(e) advertising, public relations and other promotional programs and sampling, to be used in the Co-Promotion and Co-Branding;

(f) medical affairs programs, including professional symposia and other educational activities, and medical affairs studies based upon Joint Operating Committee-approved protocols;

(g) Phase IV Clinical Trials (other than Phase IV Clinical Trials intended to support or maintain a Registration Filing for a particular IL-1 Product, including by way of example such Phase IV Clinical Trials as which are intended to support expanded labeling for such IL-1 Product or to satisfy requirements imposed by Regulatory Authorities in connection with Approvals for such IL-1 Product) in the Co-Commercialization Countries relating to the IL-1 Products, which Phase IV Clinical Trials shall be based upon JOC-approved protocols; and

 $(h) \qquad \text{ as appropriate, a training plan for the Parties'} \\ \ensuremath{\mathbb{Q}}\xspace$  Qualified Sales Representatives.

In addition to the detailed plan and budget for the next upcoming calendar year, each Country Co-Commercialization Plan, Country Co-Commercialization Budget, Consolidated Co-Commercialization Plan and Consolidated Co-Commercialization Budget will include an outline of the projected plan and estimated budget for the following calendar year.

6.6 Co-Commercialization Reports and Detailing Reports.

(a) Within thirty (30) days after the end of each quarter, Regeneron and Novartis shall each provide to the other Party and to the JOC, in electronic form a Country Co-Commercialization Report and a Consolidated Co-Commercialization Report.

(b) Regeneron and Novartis shall also each provide to the other Party and to the JOC, within thirty (30) days following the end of each quarter commencing with the first quarter during the Contract Year in which the Launch of an IL-1 Product occurs, a written report setting forth, in such detail and form as the JOC shall require, the PDEs and number of Details made by such Party's Qualified Sales Representatives in each Co-Commercialization Country during such quarter and setting out a proposed plan for future Detailing Report"). In addition, each Party shall on a periodic and reasonably current basis, keep the JOC informed regarding the activities of its Qualified Sales Representatives in promoting the IL-1 Product, including information relating to market developments, acceptance of the IL-1 Product, complaints and similar information.

-41-

6.7 IL-1 Product Pricing and Pricing Approvals. Novartis shall present to the JSC proposals for the terms and conditions of sale of each IL-1 Product in each Co-Commercialization Country, including proposed IL-1 Product pricing, pricing changes, requests for reimbursements, and parameters for any discount or rebate programs. Final decisions concerning IL-1 Product conditions of sale, pricing, and discount/rebate programs shall be made by the JSC or the applicable Country Co-Commercialization Committee, if any. In those -Commercialization Countries where Price Approval is required or determined by the JSC to be desirable, Novartis will be solely responsible for using Commercially Reasonable Efforts to seek and obtain such approval, provided that Regeneron shall have the right to participate in any material meetings or the preparation of any material submissions to Governmental Authorities in connection therewith. Regeneron (or its local Affiliate) shall be responsible for any reasonable assistance required by Novartis (or its local Affiliate) for the purposes of obtaining such Pricing Approval. In the event that, whether by failure of Novartis to exercise the Trap-2 Opt-In Rights or as a result of a termination of this Agreement with respect to any Trap-1 Product, the IL-1 Antibody Product or the Trap-2 Product, Regeneron Commercializes any of the Trap-1 Product, the IL-1 Antibody Product or the Trap-2 Product outside of the collaboration contemplated by this Agreement, Regeneron shall, to the extent necessary to comply with applicable Law, institute screening procedures to ensure that Regeneron's representation on the applicable Committees will not disclose or exchange pricing information or other competitively sensitive information with the Regeneron personnel responsible for Commercialization of such products outside of the collaboration contemplated by this Agreement.

6.8 Booking of Sales and IL-1 Product Distribution. Novartis (or its local Affiliate) shall invoice and book all sales of the IL-1 Product in the Co-Commercialization Countries and shall appropriately record all sales of the IL-1 Product in the Co-Commercialization Countries. Novartis (or its local Affiliate) shall also be responsible for the distribution of the IL-1 Product in the Co-Commercialization Countries and for paying Medicaid and other governmental rebates which are due and owing with respect to the IL-1 Product in the Co-Commercialization Countries.

6.9 Field Forces.

(a) Field Force Activities. In Co-Promoting and Co-Branding IL-1 Products in the Co-Commercialization Countries, each Party (through its local Affiliates, as appropriate) shall provide such internal administrative and logistical support of its Qualified Sales Representative field force as is usual and customary in the pharmaceutical industry in the relevant Co-Commercialization Countries, consistent with its normal practices. Each Party (through its local Affiliates, as appropriate) shall diligently Co-Promote or Co-Brand, as applicable, IL-1 Products in such country in accordance with the then-applicable Joint Steering Committee-approved Country Co-Commercialization Plans. Such efforts shall include, without limitation, performing the following types of activities, each in accordance with the approved Country Co-Commercialization Plan:

> training, maintaining and managing Qualified Sales
>  Representatives to Detail Professionals and potential purchasers, including target physicians;

(ii) distributing Promotional Materials through eachParty's respective Qualified Sales Representatives or other customarymethods;

-42-

(iii) subject to Section 6.18, responding to inquiries regarding the IL-1 Products (other than consumer and medical inquiries);

(iv) providing administrative support services (such as an electronic territory management system, where applicable); and

 (v) setting, monitoring and implementing Qualified Sales Representative incentives related to the Co-Promotion, Co-Branding and sale of the IL-1 Products,

provided, however, that in carrying out the foregoing activities hereunder with respect to IL-1 Products, neither Party shall use the services of any Person involved in the Commercialization of any Trap-1 Product, IL-1 Antibody Product or Trap-2 Product which is not an IL-1 Product subject to Co-Development and/or Co-Commercialization rights pursuant to this Agreement, if the use of such services would violate applicable Law.

(b) Cooperation. The JOC shall coordinate the Co-Promotion or Co-Branding, as the case may be, of each IL-1 Product by Novartis, Regeneron, their respective local Affiliates and their respective Qualified Sales Representatives in each Co-Commercialization Country. The Parties will discuss efforts to mirror their respective field forces, field force territories and management structures in each Co-Commercialization Country. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, alignment of the weighting of the IL-1 Product-related incentives within the Qualified Sales Representatives' overall incentives, and Professional or other customer targeting in order to optimize sales and profits under the Consolidated Co-Commercialization Plan and the relevant Country Co-Commercialization Plan. Without limiting the generality of the foregoing, the Parties will share, and, to the extent appropriate, cooperate with respect to implementing consistent, policies and procedures with respect to the manner in which Details are conducted. Following the Launch date, the Parties will discuss whether it is advisable for Regeneron to adopt and/or utilize Novartis's Sales Infrastructure Elements as part of the Consolidated Co-Commercialization Plan. Novartis shall be compensated for any services or resources provided in connection with its sharing of the Novartis Sales Infrastructure Elements on such terms mutually agreed upon by the Parties.

(c) Contract Sales Force. Either Party shall be entitled to discharge its annual Detailing obligations for any IL-1 Product in any Co-Commercialization Country by engaging a Contract Sales Force. If a Party (or its local Affiliate) retains a Contract Sales Force in a Co-Commercialization Country, that Party (or its local Affiliate) will be responsible for all costs associated with retaining such Contract Sales Force and for the Contract Sales Force's compliance with this Agreement, including, without limitation, the training and monitoring of such Contract Sales Force and ensuring compliance with all applicable Laws.

#### 6.10 Detailing.

-43-

(b) Changes in Regeneron Detailing Commitment. Regeneron may change the Regeneron Commitment Level on a product-by-product and country-by-country basis by giving [\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*] notice in writing to Novartis and to the JSC; provided, however, that in no event may the Regeneron Commitment Level exceed the Maximum Regeneron Effort, and provided, further, that any increase in the Regeneron Commitment Level shall not be effective if the JSC reasonably determines that such change would have an adverse effect on the Parties' shared goal of optimizing the commercial potential of the applicable IL-1 Product.

(d) Projected PDE Shortfalls. There may be occasions when a Party (or its local Affiliate) believes in good faith that, notwithstanding Commercially Reasonable Efforts, it will be unable to perform the number of Details for an IL-1 Product in one or more Co-Commercialization Countries for which it is responsible under the then-current Country Co-Commercialization Plans. In such an event, such Party (or its local Affiliate) (the "Shortfall Party") shall promptly give written notice to the other Party (or its local Affiliate) and the JOC that it will not be able to meet its Detailing obligations together with notice of the projected shortfall in PDEs. Upon receipt of such notice, the other Party (or its local Affiliate) shall have the option, exercisable in its sole discretion, to perform such additional PDEs, in which case (i) the Shortfall Party's minimum PDE obligation under the then-current Country Co-Commercialization Plan for purposes of determining any penalties or additional PDEs agreed to be performed by the other Party for that year, and (ii) the Shortfall Party shall reimburse the other Party for the cost of performing the additional PDEs during the relevant calendar year on a product-by-product and country-by-country basis, based upon [\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*]

-44-

(f) Detailing; Record Keeping. Each Party (through its local Affiliates where appropriate) shall maintain records of its Detailing of the IL-1 Products in the Co-Commercialization Countries in a manner sufficient to permit the determination of the number and position of Details performed by such Party with respect to the IL-1 Products in each Co-Commercialization Country. Any shortfall by a Party (or its Affiliates) in performing the number of annual PDEs specified in the Joint Steering Committee-approved Country Co-Commercialization Plan shall, at the end of each year, be addressed in accordance with the provisions of this Section 6.10. Each Party shall adopt a code of conduct for its sales force strictly and explicitly prohibiting falsification of Detail reporting and imposing penalties for non-compliance, which penalties shall be enforced.

(g) PDE Reporting. Each Party (through its local Affiliates where appropriate) shall provide the other Party and the JOC with periodic reports of the number and position of Details actually performed by it for each IL-1 Product in each Co-Commercialization Country. Such PDE reports shall be provided quarterly, within thirty (30) days after the close of the calendar quarter covered by the report; provided that more frequent reporting may be required as determined by the JOC. Notwithstanding the foregoing, during the first two (2) years immediately following the Launch of each IL-1 Product in each Co-Commercialization Country, such PDE reports shall be provided by each Party on a monthly basis, within sixty (60) days after the end of each month, with respect to the relevant Co-Commercialization Country.

6.11 Training.

(a) Each Party (through its local Affiliates where appropriate) shall, at its own expense, comply with the training plan contained in any Consolidated Co-Commercialization Plan or Country Co-Commercialization Plan.

(b) Prior to the Launch of an IL-1 Product in any Co-Commercialization Country, the Parties (through their local Affiliates where appropriate) shall jointly develop sales training materials for use in training each Party's Qualified Sales Representatives. The Parties (through their local Affiliates where appropriate) will thereafter cause their training personnel to train their field Qualified Sales Representatives with such training materials and Promotional Materials.

(c) If either Party (including through their respective local Affiliates) organizes IL-1 Product-related meetings of its employees (such as launch meetings or periodic briefings of its Qualified Sales Representatives), it will make Commercially Reasonable Efforts to give the other Party (or its local Affiliate) advance notice of such meetings. If requested by the other Party (or its local Affiliate), the Party (or its local Affiliate) organizing such meetings will permit representatives of the other Party (or its local Affiliate) to attend and participate in such meetings or such portions thereof which relate to

-45-

the Co-Commercialization of the IL-1 Products at their own cost. In such event, the Party organizing such meeting shall keep the IL-1 Product-related portions of such meetings independent from other matters.

(d) In a manner determined by the Joint Operating Committee, the Parties (through their local Affiliates where appropriate) will coordinate the Detailing, sales meetings, contacts with wholesalers and retailers, targeting of healthcare organizations, speaker programs and, as appropriate, medical affairs and/or support activities for relevant Phase IV Clinical Trials as provided in the Consolidated Co-Commercialization Plan and relevant Country Co-Commercialization Plan.

6.12 Promotional Materials. The Parties and their Affiliates shall only use JOC approved Promotional Materials and only conduct marketing and promotional activities for the IL-1 Products which, in each case, are provided for in the relevant approved Country Co-Commercialization Plan. The Parties will jointly prepare Promotional Materials for the IL-1 Products which are intended for use within the Co-Commercialization Countries. Novartis will have primary responsibility, with Regeneron's participation, for the preparation of Promotional Materials intended for use in a Co-Commercialization Country, and shall ensure that all such Promotional Materials are consistent with the approved Consolidated Co-Commercialization Plan and Country Co-Commercialization Plan, and comply with all applicable Laws. Novartis shall be responsible for the distribution of Promotional Materials for use in the Co-Commercialization Country, shall ensure that Regeneron's local Affiliates have equal access to all Promotional Materials for use in the Co-Commercialization Country, and shall treat its own Affiliates and those of Regeneron equally in connection with the distribution of Promotional Materials in accordance with the approved Country Co-Commercialization Plan. Promotional Materials which constitute Detail handouts for distribution to Professionals shall be allotted according to each Party's (or its local Affiliate's) Detail requirements under the approved Country Co-Commercialization Plan. Promotional Materials for use in Detail presentations and retained by the Qualified Sales Representatives shall be allotted according to the number of Qualified Sales Representatives to be engaged by each Party (or their respective local Affiliates) under the approved Country Co-Commercialization Plan for the relevant country. The Parties shall jointly own all rights to all Promotional Materials, including all copyrights thereto. All locally generated Promotional Materials for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved under a core review process to be established by the Joint Operating Committee.

6.13 Promotional Claims/Compliance. Neither Party (nor any of their respective Affiliates) shall make any medical or promotional claims for any IL-1 Product beyond the scope of the relevant Approval(s) then in effect for such IL-1 Product or that are beyond the scope of, or inconsistent with, the approved Consolidated Co-Commercialization Plan, Country Co-Commercialization Plans and Promotional Materials. When distributing information related to any IL-1 Product or its use (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party (and their respective Affiliates) shall comply with all applicable Laws (and with respect to the U.S., in accordance with the Pharmaceutical Research Manufacturers of America Code on Interactions with Healthcare Professionals).

6.14 Samples. In support of Regeneron's Detailing and promotional activities, Novartis shall provide Regeneron with IL-1 Product samples as required in the

-46-

Consolidated Co-Commercialization Plan. Samples shall be allotted according to the Detailing requirements of each of Novartis and Regeneron under the Consolidated Co-Commercialization Plan and applicable Country Consolidated Co-Commercialization Plan and Laws. Novartis shall supply its local Affiliate in each Co-Commercialization Country with the total number of samples required for such Co-Commercialization Country and such Novartis Affiliates shall subsequently forward to Regeneron at a designated location the number of samples to which Regeneron is entitled under the Consolidated Co-Commercialization Plan and applicable Country Consolidated Co-Commercialization Plan. Novartis and Regeneron (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable, approved Consolidated Co-Commercialization Plan and Country Co-Commercialization Plan and shall store and distribute samples in full compliance with applicable Laws, including the requirements of the PDMA. Regeneron (and is local Affiliates) will maintain those records required by the PDMA and all other Laws and shall allow representatives of Novartis to inspect such records and storage facilities for the IL-1 Product samples on request. Subject to receipt of necessary information from the other Party, the Lead Regulatory Party shall be solely responsible for the filing with the FDA of any necessary reports in connection with the PDMA.

 $\,$  6.15 Cost of Field Sales Promotion. Each Party shall be solely responsible for all costs and expenses incurred by it in providing the personnel necessary to provide the services described in this Article VI (including, without limitation, salaries, benefits, cars and customer relationship money for such personnel), other than as provided in Sections 6.10(a), (d) and (e).

6.16 Managed Care and Institutional Customers. Novartis shall be responsible for all interactions with Managed Care and Institutional Customers and for the implementation of contracting strategies and procedures developed by the JOC with respect to Managed Care and Institutional Customers.

6.17 Shared Promotion Expenses. Novartis (or its relevant local Affiliate with respect to such Affiliate's Co-Commercialization Country) and Regeneron (or its relevant local Affiliate with respect to such Affiliate's Co-Commercialization Country) shall each bear the portion of Shared Promotion Expenses accrued in implementing each applicable Consolidated Co-Commercialization Plan.

6.18 Medical and Consumer Inquiries. Each Party (through its local Affiliates, as appropriate) shall be entitled to respond to routine medical and consumer inquiries received by it concerning the IL-1 Products; provided that all such responses shall be in accordance with the approved IL-1 Product labeling information and, as appropriate, the recommendations of the JOC, and that all such inquiries and responses shall be shared, as appropriate, with the other Party to the extent not prohibited by applicable Law. Any non-standard inquiries should be directed to the attention of such person(s) as is designated pursuant to Section 7.6(a).

6.19 Compliance with Laws. Each Party shall use, and shall ensure that its Affiliates and sublicensees use, Commercially Reasonable Efforts to carry out its Commercialization activities with respect to IL-1 Products in material compliance with all applicable Laws governing the conduct of such activities, including, without limitation, all applicable export and import control laws.

-47-

6.20 Phase IV Clinical Trials. Subject to the provisions of this Agreement, the Parties shall use Commercially Reasonable Efforts to comply with any Phase IV Clinical Trial obligations, with respect to any IL-1 Product in any country in the applicable Territory, imposed by applicable Law or pursuant to the applicable Approvals. The Parties shall use Commercially Reasonable Efforts to conduct Phase IV Clinical Trials with respect to any IL-1 Product in any country in the applicable Territory which has been recommended by the JOC and which has been approved by the Joint Steering Committee.

6.21 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain and, to the extent available, legally extend the Market Exclusivity Period (other than with respect to Patent Rights, for which the provisions of Article XII shall apply), granted to a Party(ies) with respect to a Product in any country in the applicable Territory.

(a) a Trap-1 Product shall not be considered a Competing Product (i) in any Co-Commercialization Country or Co-Marketing Country in the Trap-1 Territory in which this Agreement has been terminated with respect to Trap-1 (A) by Novartis pursuant to Sections 19.3 or 19.4 or (B) by Regeneron pursuant to Sections 19.5, 19.6 or 19.7 or (ii) in any country outside the Trap-1 Territory.

(b) an IL-1 Antibody Product shall not be considered a Competing Product in any country outside of the IL-1 Antibody Territory;

(c) an IL-1 Antibody Product shall not be considered a Competing Product in the event that Regeneron does not properly exercise the IL-1 Antibody Opt-In Right;

(d) an IL-1 Antibody Product shall not be considered a Competing Product in any Co-Commercialization Country or Co-Marketing Country in the IL-1 Antibody Territory in which this Agreement has been terminated with respect to the IL-1 Antibody: (i) by Regeneron pursuant to Sections 19.3 or 19.4; or (ii) by Novartis pursuant to Sections 19.5, 19.6 or 19.7;

 (e) a Trap-2 Product shall not be considered a Competing Product in the event that Novartis does not properly exercise the Trap-2 Opt-In Right;

(f) a Trap-2 Product shall not be considered a Competing Product (i) in any Co-Commercialization Country or Co-Marketing Country in the Trap-2 Territory in which this Agreement has been terminated with respect to Trap-2 (A) by Novartis pursuant to Sections 19.3 or 19.4 or (B) by Regeneron pursuant to Sections 19.5, 19.6 or 19.7 or (ii) in any country outside the Trap-2 Territory;

(g) the provisions of this Section 6.22 shall not survive expiration of the Term of this Agreement pursuant to Section 19.2 (but shall survive termination of this Agreement in whole or in part, except as set forth in this Section 6.22); and

-48-

(h) a Party shall not be considered in breach of this Section 6.22 by reason of the acquisition by such Party of a Person if (i) the activity of such Person which would cause such breach in absence of this Section 6.22 (h) is not the primary business of such Person; (ii) 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 assets and/or activity; and (iii) 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 Commercialization of such Competing Product.

6.23 Loan Facility for Shared Promotion Expenses.

(a) General. Novartis shall create an internal loan facility from which, subject to the further provisions hereof, it shall make advances to Regeneron, and from which Regeneron may draw funds in U.S. Dollars from time to time, in amounts that in the aggregate equal up to the share of Shared Promotion Expenses incurred after 2005 and prior to the first Launch of a Trap-1 Product in connection with the Co-Commercialization of any Trap-1 Product for which Regeneron is responsible in accordance with the Agreement (the "Eligible Regeneron Promotional Expenses"). Such loan facility is referred to herein as the "Promotional Expense Facility", and such advances made thereunder are referred to herein collectively as the "Promotional Expense Facility Loans".

(b) Draws. To draw on the Promotional Expense Facility, Regeneron shall submit a notice of funding (a "Promotional Expense Facility Funding Notice") to Novartis, signed by its Chief Financial Officer, specifying the amount of the requested advance (which shall not be less than \$1 million per request) and certifying that such amount is in respect of Eligible Regeneron Promotional Expenses. Promotional Expense Facility Loans shall be made by Novartis within twenty (20) Business Days after Novartis' receipt of a Promotional Expense Facility Funding Notice.

(c) Crediting of Promotional Expense Facility Loans; Cash Disbursements. Immediately upon any Promotional Expense Facility Loan being made, Regeneron hereby authorizes and directs Novartis to, and Novartis shall, credit the amount of such Promotional Expense Facility Loan against Eligible Regeneron Promotional Expenses, and each of Regeneron and Novartis acknowledges and agrees that there will be no cash disbursements of any Promotional Expense, Facility Loans to the extent they are so applied against Eligible Regeneron Promotional Expense; provided, however, that Novartis shall disburse to Regeneron (as Regeneron may direct Novartis in a Promotional Expense, Facility Funding Notice) all or a portion of any Promotional Expense Facility Loan to the extent of Eligible Regeneron Promotional Expenses actually incurred by Regeneron or its Affiliates. Any cash disbursement of a Promotional Expense Facility Loan shall be made by Novartis by wire transfer of funds to an account specified by Regeneron in the Promotional Expense Facility Funding Notice within the time period provided in subparagraph (ii) above.

(d) Interest. The principal balance of Promotional Facility Loans outstanding shall bear interest from the date advanced at a rate per annum equal to the LIBOR Rate, plus 2.5%, and shall be compounded quarterly and, unless the Promotional Facility Loans have been accelerated in accordance with paragraph (j) below, shall be payable as provided in paragraph (e) below. Overdue principal and, to the extent permitted by law, overdue interest in respect of each Promotional Facility Loan shall, in each case, bear interest at a rate per annum equal to the rate which is 2% in excess of the rate borne by such

-49-

Promotional Facility Loan. Interest which accrues under the immediately preceding sentence shall be payable on demand.

(e) Repayment. The full amount of all outstanding Promotional Expense Facility Loans, and all accrued and unpaid interest thereon, will be due and payable three (3) years after the earlier of (A) the first Launch of a Trap-1 Product in the United States or Europe and (B) the effective date of termination of the Agreement by Novartis with respect to the entire Trap-1 Territory for all Trap-1 Products.

(f) Prepayment. Regeneron shall have the right to prepay any Promotional Expense Facility Loans prior to the time required in paragraph (e) above, without premium or penalty (except as provided below in paragraph (h)), in whole or in part, upon at least one Business Day's prior written notice (or telephonic notice confirmed by in writing, which may be by email) to Novartis of its intent to make such prepayment. The amount of any such prepayment (or repayment, whether pursuant to paragraph (e), (j) or (k) shall be applied pro rata against the principal amount of the then outstanding Promotional Expense Facility Loans and accrued and unpaid interest thereon, in the order of their dates of disbursement, with any prepayment being first applied against the longest outstanding Promotional Expense Facility Loan.

(g) Method of Repayment. Except as otherwise specifically provided herein, all payments of principal or accrued interest on Promotional Expense Facility Loans shall be made in U.S. Dollars in immediately available funds to an account of Novartis specified by it to Regeneron, and shall be paid net of withholding taxes, if applicable.

(h) Breakage Cost. Regeneron shall compensate Novartis, upon the written request of Novartis, for any expenses or costs (a reasonably detailed calculation of which shall be provided by Novartis together with such written request) incurred by Novartis as a result of any prepayment pursuant to paragraph (f) of any one or more Promotional Expense Facility Loans having occurred on a date other than the last date of a LIBOR Period relating to such Promotional Expense Facility Loans.

(i) Termination of Promotional Expense Facility. The Promotional Expense Facility shall automatically terminate, and no further Promotional Expense Facility Loans shall be advanced thereunder, upon the earlier of (A) the effective date of termination of the Agreement by Novartis with respect to the entire Trap-1 Territory for all Trap-1 Products and (B) the acceleration of the date of payment of Promotional Expense Facility Loans pursuant to subparagraph (x) below.

(j) Acceleration of Promotional Expense Facility Loans. Novartis may, by notice to Regeneron, declare all principal of, and accrued and unpaid interest on, all Promotional Expense Facility Loans due and payable, if a Post 2003/Promotional Expense Event of Default referred to in clause (A) or (B) of subparagraph (x) of Section 5.9(b) shall have occurred (and in such event upon such notice all such principal and unpaid interest shall immediately become due and payable) or if a Post 2003/Promotional Expense Event of Default referred to in clause (C) of subparagraph (x) of Section 5.9(b) shall have occurred (and in such event upon such notice all such principal and interest shall be due and payable upon the first anniversary of the date of such notice), and if a Post 2003/Promotional Expense Event of Default referred to in clause (D) of subparagraph (x) of Section 5.9(b) shall have occurred, all such principal and interest shall automatically become due and payable.

-50-

(k) Right of Set-off. In addition to any rights now or hereafter granted under applicable law or otherwise, and not by way of limitation of any such rights, if any default by Regeneron in repaying when due all principal of, and accrued and unpaid interest on, all outstanding Promotional Expense Facility Loans has occurred and is continuing, Novartis may, upon prior notice to Regeneron, set off against all such unpaid principal and interest any amount payable by Novartis to Regeneron under the Agreement.

(1) Survival. This Section 6.23 shall survive termination of this Agreement.

#### 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, with respect to the Trap-1 Product in the U.S. and the Trap-2 Product in the U.S. and shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto; provided, however, that Novartis shall perform the regulatory tasks set forth on SCHEDULE 11 with respect to the Trap-1 Product and the Trap-2 Product in the U.S., or as otherwise deemed appropriate by the JOC, provided such tasks are performed in accordance with this Agreement and applicable Law.

(b) Novartis shall be the Lead Regulatory Party, and Shall Approvals and Registration Filings, with respect to: (i) the Trap-1 Product in the Trap-1 Territory, other than in the U.S., with effect from the Effective Date; (ii) the Trap-2 Product in the Trap-2 Territory, other than in the U.S., with effect from the date of any proper exercise by Novartis of the Trap-2 Opt-In Rights; and (iii) the IL-1 Antibody Product, throughout the IL-1 Antibody Territory, and, in each case, shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto.

(c) The Lead Regulatory Party shall 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 IL-1 Product in the jurisdiction as to which it is the Lead Regulatory Party. The Lead Regulatory Party shall perform all such activities in accordance with the Joint Steering Committee-approved Consolidated Co-Development Plans and Consolidated Co-Commercialization Plans.

(b) The Parties shall establish procedures to ensure that the Parties exchange on a timely basis all necessary information to enable the Lead Regulatory Party to comply with all regulatory obligations on a global basis, including, without limitation, filing

-51-

updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements, and investigator notifications to Regulatory Authorities. The Parties shall provide to each other prompt notice of any Approval of an IL-1 Product.

(c) Notwithstanding anything herein to the contrary, the Parties shall work together cooperatively (i) in the preparation of proposed product labeling and any negotiations with Regulatory Authorities regarding IL-1 Product labeling, (ii) in the preparation of regulatory strategies with respect to all regulatory actions, communication, filings and submissions, including any supplements and amendments to Registration Filings, (iii) to prepare for Advisory Committee or any similar meeting concerning IL-1 Products, and (iv) in the response to Regulatory Authorities to any of the communications or inquiries referred to in Section 7.5(b)(i)-(vi). These regulatory matters shall be conducted with the approval and guidance of the JOC, or the Joint Regulatory Sub-Committee of the JOC, if any. The JOC (or Joint Regulatory Sub-Committee, if any) shall oversee the implementation of a plan for the registration and regulatory strategy for Registration Filings in the applicable Territory, including the schedule for such filings and submissions. All material regulatory decisions for the IL-1 Products shall be made through the JOC (or Joint Regulatory Sub-Committee, if any).

7.3 Regulatory Meetings. The Lead Regulatory Party shall be responsible for interfacing, corresponding and meeting with the applicable Regulatory Authorities with respect to each IL-1 Product in the jurisdiction as to which it is the Lead Regulatory Party. The Party which is not the Lead Regulatory Party shall have the right to have representatives participate in all material meetings and telephone discussions between representatives of the Lead Regulatory Party and applicable Regulatory Authorities with respect to each IL-1 Product.

7.4 Regulatory Correspondence. The Lead Regulatory Party shall promptly provide to the other Party copies of any material correspondence received from or submitted to the applicable Regulatory Authorities pertaining to each IL-1 Product (including, without limitation, any meeting minutes).

7.5 Assistance.

(a) Each Party shall cooperate with the other Party to provide all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Law applicable to any IL-1 Product.

(b) Such assistance and actions shall include, among other things, keeping the other Party informed, commencing within twenty-four (24) hours after notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority or other Governmental Authority, which (A) raises any material concerns regarding the safety or efficacy of any IL-1 Product, (B) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with any IL-1 Product, or (C) is reasonably likely to lead to a recall or market withdrawal of any IL-1 Product. Information that shall be disclosed pursuant to this Section 7.5(b) shall include, but not be limited to:

> (i) governmental or regulatory inspections of manufacturing, distribution or other related facilities used for any IL-1 Product;

> > -52-

 (ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) relating to any IL-1 Product;

(iii) any communication from Regulatory Authorities or other Governmental Authorities pertaining to the Manufacture, sale, promotion or distribution of any IL-1 Product;

(iv) any other Regulatory Authority or other Governmental Authority reviews or inquiries relating to any IL-1 Product;

(v) receipt of a warning letter relating to any IL-1 Product; and

(vi) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction concerning any IL-1 Product.

7.6 Pharmacovigilance and Safety Data Exchange.

(a) Each Party shall designate a qualified person responsible for pharmacovigilance in the countries in which such Party owns an Approval. Such qualified person shall be responsible for (A) the collection of adverse event reports for the relevant IL-1 Product reported to its corresponding Party and Affiliates thereof, (B) notification to the other Party of such reports in accordance with paragraph (b) below, (C) the preparation and timely submission of individual written reports to the relevant Regulatory Authority in compliance with applicable Law, (D) the preparation and timely submission of periodic safety update reports, (E) answering pharmacovigilance questions, and (F) all notifications and communications with the appropriate Regulatory Authorities relating to pharmacovigilance; provided, however, that as set forth on SCHEDULE 11, Novartis shall coordinate pharmaco-vigilance activities and submission of reports for each IL-1 Product in the applicable Territory.

(b) Each Party shall promptly notify the other Party of all material information coming into its possession during the applicable Term concerning side effects, injury, toxicity or sensitivity reactions, including non-trivial unexpected increased incidence and severity thereof, associated with commercial or clinical uses, studies, investigations or tests with IL-1 Products (animal or human), throughout the world, whether or not determined to be attributable to an IL-1 Product ("Adverse Reaction Reports"). Each Party and its Affiliates shall assist the other Party and its Affiliates by promptly obtaining any follow-up information to the initial report from the reporter as reasonably requested by the other Party or its Affiliate. Without limitation to the foregoing, the Parties shall follow the specific procedures to coordinate the timing and handling of Adverse Event Reaction Reports to be set forth in SCHEDULE 12, to ensure prompt communications of such notifications and compliance with reporting obligations to Regulatory Authorities.

#### ARTICLE VIII

#### MANUFACTURING AND SUPPLY

8.1 Supply of Clinical Supply Requirements for Trap-1 Product. Regeneron shall use Commercially Reasonable Efforts to provide an adequate and timely supply of properly forecast Clinical Supply Requirements of the Trap-1 Product in the Territory

-53-

through the earlier of the date of the first Launch of a Trap-1 Product or the date that Novartis is capable of producing such Clinical Supply Requirements following the technology transfer referred to in Section 8.2(a). Regeneron shall supply such Clinical Supply Requirements of the Trap-1 Product at Regeneron's Clinical Supply Cost for such product.

8.2 Supply of Commercial Requirements for Trap-1 Product.

(i)	[**************************************
(ii)	[**************************************
(iii)	[********;**************;; and
(iv)	[*********************************;;

SCHEDULE 7 hereto sets forth a non-binding example of the cost pricing details for the processing of the Trap-1 using the above-referenced principles. The Parties agree that the Trap-1 cost pricing details set forth in SCHEDULE 7 are for illustrative purposes only and are not binding upon Novartis and have no legal effect whatsoever.

(b) Novartis shall be responsible for manufacturing Trap-1 Product in accordance with all applicable laws, including applicable Good Manufacturing Practices. Promptly following the execution of this Agreement, the Parties will enter into a separate Quality Agreement which shall specify certain additional responsibilities between the Parties. The Quality Agreement, which shall constitute an Ancillary Agreement for purposes hereof, shall be substantially in the form annexed hereto as Exhibit A, with such changes as are mutually agreed upon by the Parties.

(c) Novartis shall notify Regeneron if it reasonably determines that it will not be able to supply, on a long term basis, the agreed upon demand forecast for the Trap-1 Product. Upon such notification and in order to avoid and mitigate a Stock-Out Event, the matter shall be referred to the JOC to determine what, if any alternative supply source of Trap-1 Product (an "Alternative Supplier) should be identified and established. The goal of the Parties in identifying an Alternative Supplier will be first to use the internal capacity of

-54-

Novartis and/or its Affiliates and/or Regeneron to fill the supply shortfall. In the event the JOC agrees to establish an Alternative Supplier, each Party shall transfer or license (on a royalty free basis) Know-How and Patent Rights necessary to transfer production to such Alternative Supplier in a timely manner and provide reasonable assistance to the Alternative Supplier to effect such transfer. Any increase in the Cost of Goods Sold and any other reasonable and direct costs directly associated with the transfer of production responsibilities to the Alternative Supplier shall be borne exclusively by Novartis.

(i)	[**************************************
(ii)	[*************************************
(iii)	[**************************************

(e) The Parties will agree upon the Trap-1 manufacturing design and build-out time line to ensure adequate quantities of the Trap-1 are available at or prior to Launch, in the Technology Transfer Agreement.

(f) In the event of a Co-Marketing, the Parties will negotiate in good faith a separate supply agreement providing for the supply of Trap-1 Product at the agreed upon price and containing terms and provisions customary for that type of agreement in the pharmaceutical industry as deemed necessary and/or required and/or advisable by the Parties.

8.3 Supply of Clinical Supply Requirements and Commercial Requirements for IL-1 Antibody Product. Novartis shall use Commercially Reasonable Efforts to provide an adequate supply of properly forecast Clinical Supply Requirements and Commercial Requirements of the IL-1 Antibody Product in the IL-1 Antibody Territory during the applicable Term of this Agreement. Novartis shall supply such Clinical Supply Requirements of the IL-1 Antibody Product at Novartis' Clinical Supply Cost for such product. Commercial Requirements of the IL-1 Antibody Product shall be provided at a price to be determined in accordance with the pricing parameters referenced in Section 8.2 above and SCHEDULE 7 for the Trap-1 Product. In the event of a Co-Marketing, the Parties will negotiate in good faith a separate supply agreement providing for the supply of product at the agreed upon price containing terms and provisions customary for that type of agreement in the pharmaceutical industry as deemed necessary and/or required and/or advisable by the Parties for the IL-1 Antibody Product.

8.4 Supply of Clinical Supply Requirements and Commercial Requirements for Trap-2 Product. Novartis shall use Commercially Reasonable Efforts to provide an adequate supply of properly forecast Clinical Supply Requirements (post Phase II Clinical Trials) and Commercial Requirements of the Trap-2 Product in the Trap-2 Territory during the applicable Term of this Agreement. Clinical Supply Requirements of the Trap-2 Product

-55-

shall be provided at Novartis' Clinical Supply Cost for such product. Commercial Requirements of the Trap-2 Product shall be provided at a price to be determined in accordance with the pricing parameters as referenced in Section 8.2 above and SCHEDULE 7 for the Trap-1 Product. In the event of a Co-Marketing, the Parties will negotiate in good faith a separate supply agreement providing for the supply of product at the agreed upon price containing terms and provisions customary for that type of agreement in the pharmaceutical industry as deemed necessary and/or required and/or advisable by the Parties for the Trap-2 Product.

#### ARTICLE IX

### PERIODIC REPORTS; PAYMENTS

9.1 Periodic Reports. During the applicable Term, Novartis and Regeneron shall each prepare and deliver to the other Party and to the JOC the periodic reports specified below in this Section 9.1:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Sections 5.8 and 6.6;

(b) Novartis shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each IL-1 Product by country in local currency and U.S. Dollars;

(c) Within thirty (30) days following the end of each calendar quarter, Novartis shall deliver electronically a written report setting forth: (i) the Net Sales of each IL-1 Product for that quarter, by dosage form and unit size, including the average sales price of each such IL-1 Product and an accounting of the deductions from Net Sales permitted by the definition thereof; and (ii) adjustments (including reimbursements or recoupment of prior deductions), if any, to Net Sales reported for any previous calendar quarter;

(d) Within thirty (30) days following the end of each calendar quarter, each Party that has incurred any Development Costs in that calendar quarter shall deliver electronically a written report setting forth the Development Costs incurred by such Party in such calendar quarter;

(e) Within thirty (30) days following the end of each calendar quarter following Launch in any Co-Commercialization Country, each Party (through their local Affiliates where appropriate) shall each deliver electronically to the other Party (or its local Affiliate) and to the JOC a quarterly Country Co-Commercialization Report for such Co-Commercialization Country. In addition, each Party (through their respective local Affiliates where appropriate) shall keep the JOC informed regarding the activities of its (or its local Affiliate's) Qualified Sales Representatives in Co-Promoting each IL-1 Product in each Co-Promotion Country and Co-Branding Country, including information relating to market developments, acceptance of such IL-1 Product, complaints concerning such IL-1 Product and similar information; and

(f) Within sixty (60) days following the end of each calendar quarter, Novartis shall deliver electronically to Regeneron a Consolidated Net Sales and Expense Report in respect of such calendar quarter, combining the information reported by each Party and showing its calculations of the amount of any payments to be made by the Parties

-56-

hereunder for such quarterly period as contemplated by Section 9.2 and, if applicable, providing for the netting of such payments.

. Such reports shall be in such form, format and level of detail as may be approved by the JOC.

9.2 Funds Flow.

(a) Target Profit Split. The Parties shall agree, through the Finance Sub-Committee, on appropriate payments to achieve the applicable Target Profit Split and sharing of costs and expenses based on the principles set forth below:

> (i) Each Party is entitled to be reimbursed for expenses incurred in accordance with the Consolidated Co-Development Plan and the Consolidated Co-Development Budget, the Country Co-Commercialization Plans and the Country Co-Commercialization Budgets, and the Consolidated Co-Commercialization Plans and Consolidated Co-Commercialization Budgets.

(ii) Development Costs shall be shared as described in SCHEDULE 4;

(iii) Detailing efforts, reimbursements and payments shall be in accordance with Section 6.10;

(iv) Net profit sharing will be calculated based on Net Sales minus COGS and Shared Promotional Expenses and shall be determined according to the Target Profit Split as described in SCHEDULE 1.

(b) Mechanism For Achieving Target Profit Split. The Parties shall agree, through the Finance Sub-Committee, on an appropriate mechanism to achieve the Target Profit Split based on the principles set forth in Section 9.2(a) above. Such mechanism shall be based on the principles set forth below:

> (i) at the local level, for Co-Commercialization Countries in which both Parties are operating, expenses and profit sharing shall be calculated and executed between local affiliates in local currency;

(ii) a virtual consolidated profit and loss statement, by Region, will be calculated in U.S. Dollars to determine each Party's share of total consolidated expenses and profits in the Territory;

(iii) final settlements/funds flows shall incorporate any amounts already shared at the local levels (converted into U.S. Dollars); and

(iv) the Finance Sub-Committee shall be responsible for developing and proposing adequate policies, procedures, templates and timelines for the implementation of Target Profit Splits and funds flow calculations and mechanics.

9.3 Royalty. If Regeneron has properly exercised the IL-1 Antibody Opt-In Rights, then with respect to Annual Net Sales of any IL-1 Antibody Product in Europe and in accordance with the terms and conditions set forth in SCHEDULE 3 hereto, Novartis shall pay to Regeneron the applicable royalty as set forth in SCHEDULE 3.

-57-

(a) In addition to the payments contemplated in Sections 9.2 and 9.3, in consideration of future Development activities to be conducted for the United States with respect to IL-1 Products, NPC shall pay to Regeneron, within three (3) Business Days of the Effective Date, an amount of US \$27 million.

(b) In addition to the payments contemplated in Sections 9.2 and 9.3 above, in consideration of the rights granted by each Party to the other hereunder, each Party shall pay to the other amounts set forth in SCHEDULE 6 upon the occurrence of the corresponding event.

9.5 Revenue and Expenses in Co-Marketing Countries. Each Party shall retain all revenues accrued by such Party (or its relevant local Affiliate) on its sales of any IL-1 Product in each Co-Marketing Country. Each Party shall be responsible for its own costs and expenses incurred with respect to any IL-1 Product in each Co-Marketing Country. Within thirty (30) days following the end of each calendar quarter following Launch in any Co-Marketing Country, each Party shall provide the JOC with a detailed report of Net Sales made by the Party or its local Affiliates in Co-Marketing Countries. The format and timing of such reports shall be as approved by the JOC.

9.6 Allocation of Costs and Expenses. As soon as practicable after the Effective Date, the Parties will agree on a method for allocating cross-region Development Costs and Shared Promotion Expenses.

9.7 Invoices and Documentation. The JOC 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, which documentation may include, without limitation, invoices, bills of account, work orders and purchase orders.

9.8 Payment Currency. All amounts due under this Agreement and any Ancillary Agreement shall be paid to the designated Party in the currency designated for that purpose by the JOC, or, in the event that no such designation has been approved by the JOC, in United States Dollars (except in the case of any payments to be made between local Affiliates of Regeneron and Novartis operating in the same Co-Commercialization Country as each other, which payments may be made in the local currency common to such Affiliates); provided that in such event payments reflecting compensation payments in particular Co-Commercialization Countries shall be netted against local Co-Commercialization expenses, to the extent possible, so as to minimize the amount to be paid 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 amount due shall be determined on the basis of Novartis' account of sales which represents the conversion of all local currency sales year-to-date to United States Dollars at a sales weighted average exchange rate for the year-to-date in which the sales are recorded.

9.9 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 from the date due until paid

-58-

at a rate equal to the sum of (i) the prime rate of interest declared from time to time by Citibank, N.A. in New York, New York, plus (ii) two percent (2%) per annum (such sum being referred to as the "Default Interest Rate").

9.10 Taxes. 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 contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. Each Party shall furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law.

#### ARTICLE X

#### DISPUTE RESOLUTION

### 10.1 Resolution of Disputes.

(a) Generally. Subject to Section 10.2(f) and Section 16.2, the Parties agree that no dispute, controversy or claim arising out of or in connection with this Agreement (or any Ancillary Agreement) or the Parties' activities hereunder (or thereunder) shall be resolved other than pursuant to Article III or Article X of this Agreement, and the Parties further agree that, subject to Section 10.2(f) and Section 16.2, in no event shall any such dispute, controversy or claim be the subject of private litigation between the Parties.

(b) Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article III shall be resolved pursuant to Article III, except to the extent such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Sections 10.1(c) and 10.2 shall apply.

(c) Legal Disputes. The Parties agree that, subject to Sections 16.2 and 10.2(f), they shall use Commercially Reasonable Efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the commencement of the Term by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within fifteen (15) days after such Legal Dispute is submitted to it, 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 thirty (30) days after such Legal Dispute is submitted to them for resolution, the Parties shall be free to resort to arbitration pursuant to Section 10.2.

10.2 Arbitration of Legal Disputes.

(a) Subject to Section 10.1(b), in the event that the Parties are unable to resolve any Legal Dispute through the procedures described in Section 10.1(c) above, the Legal Dispute shall, at the request of either Party and subject to Sections 16.2 and 10.2(f), be finally settled by arbitration in accordance with the Rules of International Arbitration (the "Rules") of the International Chamber of Commerce as presently in force.

(b) The arbitration panel shall consist of three (3) arbitrators, each of whom must have legal or business experience in pharmaceutical licensing matters and/or

-59-

pharmaceutical marketing matters, as appropriate. The arbitrators are to be selected as follows: Novartis shall nominate one such qualified arbitrator; Regeneron shall nominate one such qualified arbitrator; and the two arbitrators so nominated shall nominate a third such qualified arbitrator, who shall be the presiding arbitrator, in each case subject to confirmation by the International Court of Arbitration of the International Chamber of Commerce in Paris, France (the "ICC Court"). In the event either Novartis or Regeneron shall have failed to nominate a qualified arbitrator as provided above within fifteen (15) Business Days after the other Party shall have nominated its arbitrator, or the two arbitrators so nominated shall fail to agree on a third arbitrator as provided above within fifteen (15) days after the appointment of the second arbitrator, the second arbitrator and/or the presiding arbitrator, as the case may be, shall be appointed by the ICC Court.

(c) The place of arbitration shall be New York, New York, and the language of the arbitration shall be English.

(d) Except as otherwise provided in this Agreement, the arbitration procedure set forth in this Section 10.2 shall be the sole and exclusive means of settling or resolving any Legal Dispute.

(e) Within thirty (30) days after the third and presiding arbitrator has been confirmed by the ICC Court, the Parties shall exchange all documents in their respective possession that are relevant to the issues in dispute and not protected from disclosure by attorney-client privilege or other immunity. Each Party shall also be permitted to take sworn oral deposition of individuals, such depositions to be scheduled by mutual agreement and concluded within thirty (30) days after the exchange of documents described above. At least twenty (20) days prior to the first scheduled hearing date, the Parties shall identify the witnesses that they intend to present at the arbitration hearing and the documentation on which they intend to rely. The Parties shall use their Commercially Reasonable Efforts to conclude the arbitration hearings within six (6) months following the confirmation of the third and presiding arbitrator. The arbitrators shall issue their decision (including grounds and reasoning) in writing no later than sixty (60) days following the conclusion of the last arbitration hearing.

(f) The arbitrators shall have the power to rule on dispositive motions, including motions for summary judgment. By agreeing to arbitration, the Parties do not intend to deprive any court of competent jurisdiction of its jurisdiction to issue a pre-arbitral injunction or order for specific performance, pre-arbitral attachment or other order in aid of arbitration proceedings, and the Parties hereby consent to the jurisdiction of any such court for such purposes. Without prejudice to such provisional remedies as may be available under the jurisdiction of a national court, the arbitral tribunal shall have full authority to grant provisional remedies or to order the Parties to request that a court modify or vacate any temporary or preliminary relief issued by a such court, and to award damages for the failure of any party to respect the arbitral tribunal's orders to that effect. The award of the arbitrators shall be final and binding on the Parties and may be presented by either of the Parties for enforcement in any court of competent jurisdiction, and the Parties hereby consent to the jurisdiction of such court solely for purposes of enforcement of this arbitration agreement and any order or award entered in an arbitration pursuant hereto.

(g) The fees of the arbitrators and the other costs of such arbitration, excluding attorneys' fees which each Party shall bear, shall be borne and paid as the arbitrators determine.

-60-

#### ARTICLE XI

### TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Logos. 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. The JOC shall select, for approval by the JSC, one or more Product Trademarks (including back-up trademarks) for each IL-1 Product for use with respect to such IL-1 Product throughout the applicable Territory, it being agreed that for each IL-1 Product, the Parties will endeavor to select a single Product Trademark to be used throughout the applicable Territory (and in the case of the IL-1 Antibody Product, throughout the world); provided, however, that the Parties may, where appropriate, agree through the JSC to use different Product Trademarks for different indications of a particular IL-1 Product. Each IL-1 Product shall be promoted and sold in the Co-Promotion Countries and Co-Branding Countries under the applicable Product Trademark(s) approved by the JSC. Novartis shall have the first right to select one Product Trademark for use in each Co-Marketing Country for each IL-1 Product and Regeneron shall have the second right to select one Product Trademark for use in each Co-Marketing Country for each IL-1 Product. Any additional Product Trademarks shall be fairly allocated between Novartis and Regeneron for use in Co-Marketing Countries.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, Regeneron (or its local Affiliates, as appropriate) shall own and retain all rights to Product Trademark(s) for the Trap-1 Product and the Trap-2 Product, together with all associated domain names, trade dress, service marks, copyrights and goodwill for the Trap-1 Product and the Trap-2 Product throughout the applicable Territory, other than in the Co-Marketing Countries. Novartis (or its local Affiliates, as appropriate) shall own and retain all rights to Product Trademark(s) for the IL-1 Antibody Product, together with all associated domain names, trade dress, service marks, copyrights and goodwill for the IL-1 Antibody Product throughout the applicable Territory, other than in the Co-Marketing Countries. In the Co-Marketing Countries, each Party shall own and retain all rights to Product Trademark(s) selected by it (as set forth in Section 11.2 above), together with all associated domain names, trade dress, service marks, copyrights and goodwill in the Co-Marketing Countries.

11.4 Prosecution, Maintenance and Enforcement of Product Trademarks. Regeneron will, at its own cost and expense, use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark for the Trap-1 Product and the Trap-2 Product in the Co-Commercialization Countries of the applicable Territory for the applicable Term. Novartis will, at its own cost and expense, use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark for the IL-1 Antibody Product in the Co-Commercialization Countries of the applicable Territory for the applicable Term. Notwithstanding the foregoing, in the event either Party elects not to prosecute or maintain any Product Trademark in a Co-Commercialization Country, the other Party shall have the right to do so at its sole cost and expense, subject to consultation and cooperation with the other Party.

-61-

11.5 License to the Trap-1 and Trap-2 Product Trademarks. Regeneron hereby grants to Novartis a license to use the Product Trademark(s) for the Trap-1 Product and the Trap-2 Product in the Co-Commercialization Countries of the applicable Territory for the purposes of Novartis' Co-Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Novartis' rights under this Section 11.5 may be sublicensed, but only to Novartis' Affiliates for the purposes of, and subject to the terms and conditions of, this Agreement. Novar tis and its Affiliates shall have no rights in or to the Product Trademark for the Trap-1 Product or the Trap-2 Product or the goodwill pertaining thereto. Regeneron (and its Affiliates, as appropriate) shall own and retain all rights in and to trademark, trade dress, service marks, copyrights, and goodwill associated therewith, and all use of the Product Trademark for the Trap-1 Product and the Trap-2 Product by Novartis and its Affiliates shall, at all times inure to the benefit of Regeneron. Novartis and its Affiliates shall utilize the Product Trademark for the Trap-1 Product and the Trap-2 Product only on approved Promotional Materials or other approved product-related materials for the Trap-1 Product and the Trap-2 Product for the purposes contemplated herein. Novartis agrees that at no time during the applicable Term or thereafter, 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) for the Trap-1 Product and Trap-2 Product or take any other action which damages or dilutes the rights to, or goodwill associated with, such Product Trademarks in the applicable Co-Commercialization Countries. Subject to Article XIX, Novartis agrees that upon termination or expiration of the Term for the Trap-1 Product or the Trap-2 Product (as applicable), Novartis and its Affiliates will discontinue forthwith all use of the applicable Product Trademark. All uses by Novartis of the Product Trademark for the Trap-1 Product and the Trap-2 Product shall comply with the applicable local Law. Upon request by Regeneron, Novartis shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required by Regeneron for the purpose of recording the license, or assigning any rights in the trademark, trade dress, service marks, copyrights and set forth in this Section 11.5 above with any Governmental Authority.

11.6 License to the IL-1 Antibody Product Trademark. Novartis hereby grants to Regeneron a license to use the Product Trademark(s) for the IL-1 Antibody Product in the Co-Commercialization Countries of the applicable Territory for the purposes of Regeneron's Co-Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Regeneron's rights under this Section 11.6 may be sublicensed, but to Regeneron's Affiliates for the purposes of, and subject to the terms and conditions of, this Agreement. Regeneron and its Affiliates shall have no rights in or to the Product Trademark for the IL-1 Antibody Product or the goodwill pertaining thereto. Novartis (and its Affiliates, as appropriate) shall own and retain all rights in and to trademark, trade dress, service marks, copyrights, and goodwill associated therewith, and all use of the Product Trademark for the TT.-1 Antibody Product by Regeneron and its Affiliates shall, at all times inure to the benefit of Novartis. Regeneron and its Affiliates shall utilize the Product Trademark for the IL-1 Antibody Product only on approved Promotional Materials or other approved product-related materials for the IL-1 Antibody Product for the purposes contemplated herein. Regeneron agrees that at no time during the applicable Term or thereafter, 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) for the IL-1 Antibody Product or take any other action which damages or dilutes the rights to, or goodwill associated with, such Product Trademark(s) in the explicited of the service of the applicable Co-Commercialization Countries. Subject to Article XIX, Regeneron agrees that upon

-62-

termination or expiration of the Term for the IL-1 Antibody Product, Regeneron and its Affiliates will discontinue forthwith all use of the Product Trademark. All uses by Regeneron of the Product Trademark for the IL-1 Antibody Product shall comply with the applicable local Law. Upon request by Novartis, Regeneron shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required by Novartis for the purpose of recording the license, or assigning any rights in the trademark, trade dress, service marks, copyrights and set forth in this Section 11.6 above with any Governmental Authority.

11.7 Use of Corporate Names. Each Party (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include the other Party's name (or such other Party's local Affiliate's name) with equal prominence on materials related to each IL-1 Product (including, without limitation, package inserts, packaging, trade packaging, samples, and all Promotional Materials used or distributed in connection with the applicable IL-1 Product) in the Co-Commercialization Countries in the applicable Territory, unless to do so would be prohibited under applicable Laws. Accordingly, each Party grants to the other (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and on all Promotional Materials used or distributed in connection with the applicable IL-1 Product in the Co-Commercialization Countries in the applicable Territory during the applicable Term and thereafter for a period of one (1) year with respect to advertising and Promotional Materials, and for a period of two (2) years with respect to package inserts, packaging, labeling, trade packaging, samples, or until the existing inventory of such IL-1 Product and Promotional Materials is exhausted, whichever is earlier.

#### ARTICLE XII

#### NEWLY CREATED INVENTIONS

## 12.1 Ownership of Newly Created Intellectual Property.

(a) Sole Inventions. Each Party shall exclusively own all intellectual property (including, without limitation, data, discoveries, technical information, Know-How, patents, patent applications, proprietary information, trade secrets and inventions) invented or generated solely by such Party, its employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Novartis, its employees, agents and consultants are referred to herein as "Novartis Sole Inventions." Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as "Regeneron Sole Inventions."

(b) Joint Inventions. The Parties shall jointly own all intellectual property (including, without limitation, data, discoveries, technical information, Know-How, patents, patent applications, proprietary information, trade secrets and inventions) invented or generated jointly by an individual or individuals having an obligation to assign such intellectual property to Novartis, on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron, on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions").

(c) Inventorship. Notwithstanding the above, for purposes of determining whether a patentable invention is a Novartis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, and, for purposes of determining whether a copyrighted work is a Novartis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship

-63-

shall be resolved in accordance with United States copyright laws, provided, further, that nothing in this Article XII shall relieve a Party or its Affiliates of their obligations under Article XVI with respect to confidential Company Information provided by the other Party or such other Party's Affiliates.

#### 12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron Solely-Owned Patent Rights. Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain, at its own cost and expense, Patents and Patent Applications (as applicable) within the Regeneron Patent Rights throughout the applicable Territory, and shall confer with and keep Novartis reasonably informed regarding the status of such activities. Regeneron shall have the exclusive right and option, at its own cost and expense, to file and prosecute any Patent Applications covering Regeneron Sole Inventions, and to maintain any Patents issuing thereon. Notwithstanding the foregoing, if Regeneron elects not to prosecute or maintain any Regeneron Patent Right, Novartis will have the right to do so at Novartis' sole cost and expense, and Regeneron will assign such Patent Rights to Novartis.

(b) Novartis Solely-Owned Patent Rights. Novartis shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain, at its own cost and expense, Patents and Patent Applications (as applicable) within the Novartis Patent Rights throughout the applicable Territory, and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. Novartis shall have the exclusive right and option, at its own cost and expense, to file and prosecute any Patent Applications covering Novartis Sole Inventions, and to maintain any Patents issuing thereon. Notwithstanding the foregoing, if Novartis elects not to prosecute or maintain any Novartis Patent Right, Regeneron will have the right to do so at Regeneron's sole cost and expense, and Novartis will assign such Patent Rights to Regeneron.

Joint Patent Rights. With respect to any Joint Patent (C) 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 (i) the Controlling Party shall permit the non-Controlling Party to review and comment at least two (2) weeks prior to the filing of any priority Patent Application by the Controlling Party; (ii) the Controlling Party shall notify the non-Controlling Party within thirty (30) days after the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall notify the non-Controlling Party within eight (8) months from the filing of the priority Patent Application whether and in which countries it intends to 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 (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

-64-

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 ninety (90) days of a written request by the non-Controlling Party to do so, 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, providing a free-of-charge option to assume the prosecution or maintenance thereof. The Parties agree that any of the periods of time specified in this Section 12.2(c) shall be shortened as may be required to ensure that rights in the relevant Joint Patent Right are not lost. All out-of-pocket costs incurred in the filing, prosecution and maintenance of any Joint Patent Rights shall be treated as a Shared Promotion Expense shared between the Parties as set forth in Section 9.2(c).

(d) Cooperation. 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(b). The IPSC shall recommend to the JOC which of the Novartis Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term. Upon confirmation of the recommendation of the IPSC with respect to patent term extension, and the Parties shall bear the costs thereof in the same manner as the Parties bear the expenses for the filing, prosecution and maintenance of such Patent Rights in accordance with the provisions of this Section 12.2.

#### 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 infringement of a Novartis Patent Right, a Regeneron Patent Right, or a Joint Patent Right by a Third Party's activities in the applicable 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 IPSC to meet and consider the appropriate course of action with respect to such infringement.

(b) With respect to any infringement by virtue of a Third Party's activities with respect to a product which is a Competing Product, the IPSC will determine whether infringement litigation or settlement discussions with the infringer should be undertaken. If the IPSC decides that any such infringement litigation should be undertaken, the IPSC will also decide which Party is to be the Lead Litigation Party ("Lead Litigation Party"). The

-65-

Lead Litigation Party will have the right bring and prosecute, or defend, such infringement suits as may be necessary to cause the infringer to cease activities with respect to any such Competing Product, the manufacture, use, sale, offer for sale or import of which would infringe said Novartis Patent Right, Regeneron Patent Right, or Joint Patent Right in the applicable Territory. Upon confirmation of the IPSC decision by the JOC, the Lead Litigation Party will bring and prosecute an infringement suit, and/or defend a declaratory judgment action, as appropriate, against such infringing Third Party. The Lead Litigation Party will select litigation counsel of its choosing. The Lead Litigation Party will pay all litigation costs. 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. The non-Lead Litigation Party shall have the right to join in any litigation at its sole discretion and expense. The amount of any recovery from any such infringement suit, whether in damages or by settlement, will be included in the Net Sales figure for such Co-Commercialization Country for the quarter in which the recovery is paid to the Lead Litigation Party. In the event that there is more than one IL-1 Product at the time of such recovery, then the amount of any such recovery shall be allocated between such IL-1 Products as determined by the IPSC.

(c) With respect to any infringement by virtue of a Third Party's activities with respect to any product which is not a Competing Product, then (i) Regeneron, with respect to any Regeneron Patent Rights, (ii) Novartis with respect to any Novartis Patent Rights, and (iii) either Party, with respect to any Joint Patent Rights, shall have the right (but not the obligation to bring and prosecute an infringement suit, and/or defend a declaratory judgment action, as appropriate, against such infringing Third Party. The other Party will provide reasonable assistance to the litigating Party, at the litigating Party's reasonable expense, in prosecuting any suit, and if required by law, will join in the suit. All amounts received by way of any recovery from any such infringer, whether in damages or by settlement, shall be to the benefit of the litigating Party.

13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which an IL-1 Product is made, offered for sale, sold or imported by such Party, its Affiliates and/or sublicensees.

13.3 Third Party Infringement Claims.

(a) The provisions of this Section 13.3 shall be subject to the provisions of Article XVII, which shall govern as to both costs and procedures in the event of infringement actions relating to any IL-1 Product brought by a Third Party against either Party in which the Third Party claim(s), if true, would constitute a breach of representation or warranty set forth in Section 15.2.

(b) If either Party or its Affiliates shall learn of a claim or assertion that the manufacture, Development or Commercialization of any IL-1 Product infringes or otherwise violates the intellectual property rights of any Third Party, then such Party shall promptly notify the other Party in writing of this claim or assertion. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the IPSC to meet and consider the appropriate course of action with respect to such allegation of infringement.

(c) If only one Party defends any claimed infringement action commenced by a Third Party alleging that the manufacture, Development or Commercialization of any IL-1 Product infringes or otherwise violates the intellectual property rights of such Third

-66-

Party, the other Party and its Affiliates shall assist and cooperate in any such infringement litigation at the defending Party's (or its Affiliates') reasonable request.

13.4 Amgen License. During the term of this Agreement, Novartis agrees and covenants to the extent permitted by applicable Law that it shall not institute or prosecute any claim, action, or suit at law or in equity seeking to have any claim in any "Immunex IL-1r Patent Right" or "Amgen Licensed Patent Right" (as each such term is defined in the Amgen License Agreement) declared invalid or unenforceable; provided, however, that nothing herein shall prohibit Novartis from either (i) asserting any and all defenses available to it if it is sued for infringement, including, without limitation, assertions relating to the validity or enforceability of the Immunex IL-1r Patent Rights and/or Amgen Licensed Patent Rights, or (ii) asserting any and all defenses, evidence, and arguments, including, without limitation, lack of patentability of the subject matter of a count or claim and lack of support for a count or claim, in any interference involving a Patent or Patent Application included within the definition of Immunex IL-1r Patent Rights or Amgen Licensed Patent Rights.

#### 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 IAS or GAAP (as applicable, depending on which accounting principles such entity uses to maintain its accounting books and records) as generally and consistently applied and all requirements of Law) shall be made of all dealings and transactions in relation 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 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 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 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 under this Agreement, including, without limitation, the numbers of Details, the reports and payments provided under this Agreement and corresponding provisions of the Ancillary Agreements (for greater clarity, the Parties agree that the establishment of COGS shall not be subject to this Article XIV). Audits under this Section 14.2 shall not be based on data provided by Third Party data sources.

(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

-67-

any such audit shall be subject to the dispute resolution procedures set forth in Section 10.2. If the audited Party or its Affiliates have underpaid or overbilled 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 XVI.

(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 (or its Affiliate) owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment or overpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party (or its Affiliate) entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section. In the event that any examination or audit of Detailing records indicates a shortfall in the number of Details carried out by a Party or its Affiliate, the amount due in relation to such shortfall shall be calculated and paid in accordance with the provisions of Section 9.2(a) (iii) and Section 6.10 above.

14.3 Accounting Standards. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with International Accounting Standards 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 follows: (a) it is duly organized and validly existing under the Laws of its place 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 material agreement or arrangement, whether written or oral, by which it is bound; (d) to the best of its knowledge, it has complied in all material respects with all Laws applicable to it; (e) 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); 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.

15.2 Intellectual Property.

-68-

Product or Trap-2 Product nor the Development, promotion, marketing and sale of any the Trap-1 Product or Trap-2 Product by the Parties will infringe upon any valid rights of any other Person and it has not received any written notice alleging any such infringement, (c) the rights granted by Regeneron to Novartis and its Affiliates hereunder do not, to Regeneron's knowledge, conflict with rights granted by Regeneron to any Third Party and (d) Regeneron has not received any notice concerning the institution or possible institution of any interference involving any Regeneron Patent, nor has it made any application for reissuance or filed any request for reexamination with respect to any such Patent.

(b) Novartis represents and warrants to Regeneron that, as of the Effective Date, (a) [\*], it owns or has all necessary licenses or rights within its jurisdiction to use the IL-1 Antibody Product, (b) [\*], neither the manufacturing of the IL-1 Antibody Product nor the Development, promotion, marketing and sale of the IL-1 Antibody Product by the Parties will infringe upon any valid rights of any other Person and it has not received any written notice alleging any such infringement, (c) the rights granted by Novartis to Regeneron and its Affiliates hereunder do not, to Novartis' knowledge, conflict with rights granted by Novartis to any Third Party and (d) Novartis has not received any notice concerning the institution or possible institution of any interference involving any Novartis Patent and nor has it made any application for reissuance or filed any request for reexamination with respect to any such Patent.

15.3 Disclaimer. Except as expressly set forth herein, no Party makes any express or implied warranties, statutory or otherwise, concerning the value, adequacy, freedom from fault of, other quality, efficiency, stability, characteristics or usefulness of, or merchantability, or fitness for a particular purpose of, any IL-1 Product.

# ARTICLE XVI

### CONFIDENTIALITY

### 16.1 Confidential Company Information.

(a) Each of Novartis and Regeneron acknowledges (subject to Section 16.1(b)) that: (i) all Company Information provided by the other Party or its respective Affiliates pursuant to this Agreement is confidential and proprietary to such other Party or its respective Affiliates, and (ii) all New Information is confidential and proprietary to the Parties, and each of Novartis and Regeneron agrees to (A) maintain such information in confidence during the last to expire Term of this Agreement and for a period of ten (10) years thereafter and (B) use such information solely for the purpose of performing its obligations hereunder. Each of Novartis and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such information to any Third Party except to its employees, agents or any other person under its authorization; provided such employees, agents or persons under its authorization are subject in writing to substantially the same confidentiality obligations as the Parties and their respective Affiliates.

(b) Notwithstanding anything provided above, the restrictions provided in this Article XVI shall not apply to information that 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 by reason of prior publication or otherwise; (ii) received by a receiving Party 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; (ii) information that has become part of the public domain after the Effective

-69-

Date through no act, omission or fault of the receiving Party; or (iv) information that is similar in nature to the purported Company Information but has been independently created, as evidenced by written or electronic documentation. If a receiving Party is required by applicable Law to disclose any Company Information to a Governmental Authority, then the receiving Party shall promptly notify the disclosing Party of such disclosure and the procedures, such as a protective order, instituted to protect the confidentiality of the Company Information to be disclosed.

(c) Notwithstanding anything provided above, Regeneron shall have the right to disclose to any Regeneron licensee of Trap-1 or Trap-2 in Japan: (i) such information as to adverse events and safety as is required under applicable Laws; and (ii) such information as is included in a top-level report summarizing Clinical Trials planned and underway with respect to Trap-1 and/or Trap-2 pursuant to this Agreement, which report shall be prepared by Novartis for purposes of this Section 16.1(c) and shall refer expressly to this Section 16.1(c); provided, however, that any such disclosure of information shall be subject to confidentiality obligations on the part of such licensee reasonably satisfactory to Novartis.

16.2 Injunctive Relief. Each Party acknowledges that damages resulting from disclosure of Company Information would be an inadequate remedy and that, notwithstanding the provisions of Article X, in the event of any such disclosure or any indication of an intent to disclose such information, a Party (or its Affiliates) owning such Company Information, and 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 hereby consent to the jurisdiction of such for such purpose and will not assert as a defense that there is an adequate remedy at law.

16.3 Publication of New Information. Subject to JOC approval, if either Novartis or Regeneron (the "Publishing Party") desires to disclose any New Information or such other Company Information which relates to any IL-1 Product in scientific journals, publications or scientific presentations or otherwise, 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 or such other Company 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 preserve the New Information or such other Company Information, and the incorporation of such recommended changes shall not be unreasonably refused. If such other Party informs the Publishing Party, within thirty (30) days of receipt of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment could be expected to have a material adverse effect on the commercial value of any New Information or such other Company Information, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timelv preparation and filing of a patent application (s) or application (s) for a certificate of invention on the information involved, provided, however, that the Party owning such information shall be entitled to prevent such disclosure or publication if in its commercially reasonable judgment such patent application will not reasonably protect the commercial value of such New Information or Company Information or if in its commercially reasonable judgment such disclosure or

-70-

publication would otherwise have a material adverse effect on the commercial value of any such information.

16.4 Other Publications. During the Term, Novartis and Regeneron agree not to issue any press releases or public announcements concerning this Agreement, the Stock Purchase Agreement or any Ancillary Agreement (and to ensure that their respective Affiliates do not do so) without the prior written consent of the other Party to the form, timing and content of any such release of announcement, except as required by a Governmental Authority and applicable Law; provided, however, that either Party may issue press releases or public announcements which incorporate information concerning this Agreement which information was included in a press release or public announcement which was approved by the other Party as an initial press release concerning this Agreement. Neither Party shall unreasonably withhold or delay its consent to any such press release or announcement. Except as required by Law, 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 XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

## ARTICLE XVII

## INDEMNITY

### 17.1 Indemnity and Insurance.

(a) Each Party shall indemnify and hold harmless the other Party, its Affiliates and their respective officers, directors, employees and agents from and against all claims, demands, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), arising out of:

> (i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of the Indemnifying Party or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, distributors, representatives or other persons or entities working on their behalf), including, without limitation, in connection with the Co-Development and Co-Commercialization of any IL-1 Product, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by the Indemnified Party or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, representatives or other persons or entities working on their behalf); and

> (ii) breach by the Indemnifying Party (or conduct by any of its Affiliates, which if performed by the Indemnifying Party would be a breach by the Indemnifying Party) of the terms of, or the representations and warranties made by it in, this Agreement or any applicable Ancillary Agreement to which it is a party; provided, however, that the payments and adjustments provided for in Section 9.2 (a) (iii) and Section 6.10 shall be the exclusive remedy with respect to any shortfall in the provision of Details.

(b) Each Party will maintain, or self-insure for, product liability insurance to cover liabilities related to the development, manufacture, Co-Commercialization, marketing, distribution, sale and use of IL-1 Products at a commercially reasonable level.

-71-

#### 17.2 Indemnity Procedure.

(a) The Party entitled to indemnification under this Article XVII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within ten (10) 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.

(b) 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) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified Party.

(c) 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 Party and the Indemnified Party.

## ARTICLE XVIII

## FORCE MAJEURE

In the event of strikes, lock-outs or other industrial disturbances, rebellions, mutinies, epidemics, landslides, lightning, earthquakes, fires, storms, floods, sinking, drought, civil disturbances or explosions, acts or decisions of duly constituted municipal, state or national Governmental Authorities or of courts of Law, as well as impossibility to obtain equipment, supplies, fuel or other required materials, in spite of having acted with commercially reasonable diligence, or by reason of any other causes which are not under the control of the Party requesting the abatement of the performance or causes due to circumstances which could not reasonably be foreseen and which are not possible to eliminate or overcome with due diligence by such Party ("Force Majeure"), the Parties agree that, if either Novartis or Regeneron finds itself wholly or partially unable to fulfill its respective obligations in this Agreement by reasons of Force Majeure, the Party affected will advise the other Party in writing of its inability to perform, giving a detailed explanation of the occurrence of the event which excuses performance as soon as possible after the cause or event has occurred. If such notice is given, the performance of the Party giving the notification, except the payment of funds, shall be abated, and any time deadlines shall be extended for so long as performance may be prevented by Force Majeure. Except for the payment of funds that are or become due

-72-

and payable, neither Party shall be required to make up any performance that was prevented by Force Majeure. In no event will any Force Majeure extend beyond one hundred eighty (180) days.

### ARTICLE XIX

### TERM AND TERMINATION

19.1 Term. The "Term" of this Agreement shall commence on the Effective Date and shall expire on a country-by-country and product-by-product basis pursuant to Section 19.2 below, unless sooner terminated as provided herein. This Agreement may not be terminated except as specifically provided in this Agreement, and to the extent this Agreement is terminated as specifically provided in this Agreement, the "Term" shall be deemed to have terminated to the same extent.

### 19.2 Expiration of Term.

(a) Expiration of Term. The Term of this Agreement shall expire with respect to a particular IL-1 Product on a country-by-country basis in each country in the applicable Territory for such IL-1 Product, (i) at such time as, after annual (based on a calendar year) gross sales of such IL-1 Product in such country have exceeded \$1 million, such annual gross sales of such IL-1 Product in such country fall below \$1 million (unless such decline of such annual gross sales of such IL-1 Product in such country to below \$1 million is due to in whole or in part to conditions which are reasonable likely not to be of a long-term nature); or (ii) as otherwise agreed by the Parties as evidenced in writing.

(b) Effect of Expiration of Trap-1 Term. Upon expiration of the Term of this Agreement with respect to the Trap-1 Product in a country as contemplated by Section 19.2(a), all licenses and rights with respect to the Trap-1 Product in such country granted to Novartis hereunder shall automatically terminate and revert to Regeneron and in such event, the provisions of Part A of SCHEDULE 19 shall apply with respect to the Trap-1 Product in such country as if the Trap-1 Product is a "Terminated Product".

(c) Effect of Expiration of IL-1 Antibody Term. Upon expiration of the Term of this Agreement with respect to the IL-1 Antibody Product in a country as contemplated by Section 19.2(a), all licenses and rights with respect to the IL-1 Antibody Product in such country granted to Regeneron hereunder shall automatically terminate and revert to Novartis and in such event, the provisions of Part B of SCHEDULE 19 shall apply with respect to the IL-1 Antibody Product is a "Terminated Product".

(d) Effect of Expiration of Trap-2 Term. Upon expiration of the Term of this Agreement with respect to the Trap-2 Product in a country as contemplated by Section 19.2(a), all licenses and rights with respect to the Trap-2 Product in such country granted to Novartis hereunder shall automatically terminate and revert to Regeneron and in such event, the provisions of Part A of SCHEDULE 19 shall apply with respect to the Trap-2 Product in such country as if the Trap-2 Product is a "Terminated Product".



(a) Upon the mutual agreement of the Parties, this Agreement may be terminated on a product-by-product basis with respect to the entire Territory for a particular IL-1 Product, on the occurrence of one or more of the following events:

> (i) formulation failure for such IL-1 Product, including, without limitation, technical failure during development of drug product and/or formulation, unacceptable levels of degradation products (whether unacceptable for regulatory Approvals or toxicologically unacceptable), or drug product performance failing to meet the requirements of Regulatory Authorities;

(ii) unacceptable safety concerns with respect to such IL-1 Product;

(iii) failure to meet the Trial Success Criteria established by the JOC for Phase II Clinical Trials for such IL-1 Product;

(iv) unacceptable outcome of meetings with FDA and/or EMEA to define the scope of the Phase III Clinical Trials for such IL-1 Product; or

(v) failure to meet the Trial Success Criteria established by the JOC for Phase III Clinical Trials for such IL-1 Product.

In the event of any termination of this Agreement by mutual agreement of the Parties with respect to an IL-1 Product pursuant to this Section 19.3, as part of such mutual agreement: (i) the Parties shall agree upon an orderly wind down of all Development activities for the terminated IL-1 Product (including, without limitation, those being performed by their Affiliates or Third Party contractors) and each Party shall make all payments due and owing to one another and to Third Parties, provided, however, that if so provided in such mutual agreement, no Party shall be required to pay to the other Party any milestone payment pursuant to Section 9.4 with respect to the terminated IL-1 Product; and (ii) all licenses and rights with respect to the terminated IL-1 Product granted by one Party to the other Party hereunder shall automatically terminate and revert to the granting Party.

(b) If on the occurrence of one or more of the events with respect to an IL-1 Product described in Section 19.3(a) above, the Parties are unable to reach mutual agreement regarding termination of this Agreement with respect to such IL-1 Product, then a Party may terminate this Agreement with respect to the entire Territory for such IL-1 Product, provided that any such termination shall require the notice, and shall otherwise be treated for all purposes as, and shall be subject to all of the terms and conditions applicable to, terminates this Agreement with respect to an IL-Product as described above in this Section 19.3(b) due to perceived unacceptable safety concerns, including safety related issues associated with the formulation of drug product, the other Party shall indemnify the terminating Party from and against any and all Damages arising out of Third Party claims relating to such safety concerns or issues which are based upon the other Party's continuing efforts during the Trap-1 Termination Notice Period, as applicable, in support of the continued Development and/or Commercialization of such IL-1 Product.

-74-

#### 19.4 Termination Without Cause.

(a) Trap-1. Novartis may terminate this Agreement with respect to the entire Territory for all Trap-1 Products on (i) nine (9) months' written notice to Regeneron at any time prior to the first Launch of a Trap-1 Product in the Trap-1 Territory; and (ii) twelve (12) months' written notice to Regeneron at any time after the first Launch of a Trap-1 Product in the Trap-1 Except as otherwise provided below in this Section 19.4(a), Territory. Agreement shall continue in full force and effect with respect to the Trap-1 Product through the applicable notice period set forth above (the "Trap-1 Termination Notice Period"), provided that Novartis shall not be required to pay to Regeneron any milestone payment in respect of the Trap-1 Product which is achieved during the Trap-1 Termination Notice Period. Upon expiration of the Trap-1 Termination Notice Period, or earlier to the extent provided below in this Section 19.4(a), all licenses and rights with respect to the Trap-1 Product in such country granted to Novartis hereunder shall automatically terminate and revert to Regeneron (except to the extent required by Novartis to fulfill its folligations pursuant to Part A of SCHEDULE 19, and upon the earlier of such fulfillment or written notice from Regeneron that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), and the provisions of Part A of SCHEDULE 19 shall apply with respect to the Trap-1 Product in such country as if the Trap-1 Product is a "Terminated Product". During the Trap-1 Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Novartis hereunder (i) such licenses and rights granted to Novartis shall automatically terminate as of a date specified in such notice(s) (but not later than the Trap-1 Termination Notice Period) and (ii) Novartis will promptly take the actions required by Part A of SCHEDULE 19 to facilitate Regeneron's (or its nominee's) expeditious assumption during the Trap-A Termination Notice Period, with as little disruption as reasonably possible, of the continued Development and/or Commercialization of Terminated Product(s).

(b) IL-1 Antibody. Regeneron may terminate this Agreement with respect to the entire Territory for IL-1 Antibody Products, on (i) nine (9) months' written notice to Novartis at any time prior to the first Launch of such IL-1 Antibody Product in the IL-1 Antibody Territory, and (ii) twelve (12) months' written notice to Novartis at any time after the first Launch of such IL-1 Antibody Product in the IL-1 Antibody Territory. Except as otherwise provided below in this Section 19.4(b), the Agreement shall continue in full force and effect with respect to the IL-1 Antibody Product through the applicable notice period set forth above (the "IL-1 Antibody Termination Notice Period"), provided that Regeneron shall not be required to pay to Novartis any milestone payment in respect of the IL-1 Antibody Product which is achieved during the IL-1 Antibody Termination Notice Period. Upon expiration Antibody Termination Notice Period, or earlier to the extent provided below in this Section 19.4(b), all licenses and rights with respect to the IL-1 Antibody Product in such country granted to Regeneron hereunder shall automatically terminate and revert to Novartis (except to the extent required by Regeneron to fulfill its obligations pursuant to Part B of SCHEDULE 19, and upon the earlier of such fulfillment or written notice from Novartis that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Novartis), and the Provisions of Part B of SCHEDULE 19 shall apply with respect to the IL-1 Antibody Product in such country as if the IL-1 Antibody Product is a "Terminated Product". During the IL-1 Antibody Termination Notice Period, to the extent set forth or requested in a written notice from Novartis to Regeneron (i) such licenses and rights granted to Novartis hereunder shall automatically terminate as of a date specified in such notice (but not later than the II-1

-75-

Antibody Termination Notice Period) and (ii) Regeneron will promptly take the actions required by Part A of SCHEDULE 19 to facilitate Novartis' expeditious assumption during the IL-1 Antibody Termination Notice Period, with as little disruption as a reasonably possible, of the continued Development and/or Commercialization of Terminated Products.

(c) Trap-2. Novartis may terminate this Agreement with respect to the entire Territory for all Trap-2 Products on (i) nine (9) months' written notice to Regeneron at any time prior to the first Launch of a Trap-2 Product in the Trap-2 Territory; and (ii) twelve (12) months' written notice to Regeneron at any time after the first Launch of a Trap-2 Product in the Trap-2 Territory. Except as otherwise provided in this Section 19.4(c), the Agreement shall continue in full force and effect with respect to the Trap-2 Product through the applicable notice period set forth above (the "Trap-2 Termination Notice Period"), provided that Novartis shall not be required to pay to Regeneron any milestone payment in respect of the Trap-2 Product which is achieved during the Trap-2 Termination Notice Period. Upon expiration of the Trap-2 Termination Notice Period. Upon expiration of the Trap-2 Terminate and rights with respect to the Trap-2 Product in such country granted to Novartis hereunder shall automatically terminate and revert to Regeneron (except to the extent required by Novartis to fulfill its obligations pursuant to Part A or SCHEDULE 19, and upon earlier of such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), and the provisions of Part A of SCHEDULE 19 shall apply with respect to the Trap-2 Product in such country as if the Trap-2 Product is a "Terminated Product".

19.5 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.5, this Agreement shall be terminable by a Party on a product-by-product basis with respect to the entire Territory for a particular IL-1 Product, or on a country-by-country basis with respect to any particular Co-Promotion Country, Co-Branding Country or Co-Marketing Country, upon written notice to the other Party, (i) with respect to the entire Territory for a particular IL-1 Product, if the other Party commits a material breach of this Agreement that is material to the Parties' collaboration with respect such IL-1 Product as contemplated by this Agreement taken as a whole, or (ii) with respect to a particular Co-Promotion Country, Co-Branding Country or Co-Marketing Country for a particular IL-1 Product if the other Party commits material breach of this Agreement that is material to the Parties' collaboration with respect to such IL-1 Product in such Co-Promotion Country, Co-Branding Country or Co-Marketing Country, as applicable, as contemplated by 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 (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 diligent 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 diligent 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). As

-76-

used in this Section 19.5, the term "material breach" shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the other Party from the collaboration hereunder, such that termination of this Agreement, and the consequences thereof provided for herein, are appropriate and equitable remedies. Notwithstanding any term or provision this Agreement, in no event will a Party's failure to provide Details, for any reason, or no reason, constitute a material breach for purposes of this Agreement in whole or in part.

19.6 Insolvency. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (i) 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, or (ii) if the other Party proposes a written agreement of composition or extension of its debts, or (iii) 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 within sixty (60) days after the filing thereof, or (iv) if the other Party shall propose or be a party to any dissolution or liquidation, or (v) if the other Party shall make an 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(52) of the U.S. Bankruptcy Code. The 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.

### 19.7 Termination for Change of Control.

(a) Within ninety (90) days following consummation of a Change of Control of Regeneron which results in Regeneron being owned or controlled by a major Third Party pharmaceutical company with an annual turnover in excess of \$10 billion, Novartis shall have the right to notify Regeneron of its intent to terminate this Agreement in its entirety (the "Change of Control Notice"). Following delivery of the Change of Control Notice, the Parties will negotiate in good faith to enter into an exclusive license agreement pursuant to which Novartis will be granted exclusive rights to manufacture, Develop and Commercialize the IL-1 Products in the applicable Territory on mutually agreed terms. The license shall be subject to a royalty based on net sales which shall, to the greatest extent possible, mirror the economic terms set forth in the Agreement over the lives of the applicable IL-1 Products. The royalty rates and other payments shall be dependent upon the stage of Development and/or Commercialization of the IL-1 Products and the anticipated future profitability of such IL-1 Products and shall also take into account the efforts and expenses to be incurred by Novartis in Developing and Commercializing the IL-1 Products. The royalty rate and other terms and conditions shall be determined by the mutual agreement of the Parties after good faith negotiations provided, however, that if the Parties are unable to reach mutual agreement thereon within three (3) months after delivery of the Change of

-77-

Control Notice, the matter shall be submitted for arbitration in accordance with the terms of Article X hereof. The license agreement shall require the transfer to Novartis of Regeneron's sales force dedicated to Detailing of the IL-1 Products. For the avoidance of doubt, if no Change of Control Notice is received by Regeneron within ninety (90) days following a Change of Control, the Agreement shall remain in full force and effect.

(b) Regeneron will have the right to terminate this Agreement on reasonable written notice upon a Change of Control of Novartis where such Change of Control results in Novartis being owned or controlled by a major Third Party pharmaceutical company with an annual turnover in excess of \$10 billion which is commercializing a Competing Product or has a Competing Product in Phase III Clinical Trials at the time of such Change of Control.

(c) Regeneron will have the right to terminate this Agreement on a product-by-product basis with respect to the entire Territory, for a particular IL-1 Product or on a country-by-country basis with respect to any particular Co-Promotion Country, Co-Branding Country or Co-Marketing Country, or in its entirety, upon written notice to Novartis, if Novartis shall have breached any provision of Article 2 of the Registration Rights Agreement.

 $$19.8\ {\rm Effect}$  of Termination for Material Breach, Insolvency, Change of Control or Breach of Standstill Provisions.

(a) Upon termination of this Agreement by Regeneron pursuant to Section 19.5, 19.6 or 19.7(b) or (c), the provisions of Part A of SCHEDULE 19 shall apply with respect to the each terminated IL-1 Product on a country-by-country basis, if applicable, as if the terminated IL-1 Product is a "Terminated Product", and except to the extent required by Novartis to fulfill its obligations pursuant to Part A of SCHEDULE 19 (and upon the earlier of such fulfillment or written notice from Regeneron that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), all licenses and rights with respect to the terminated IL-1 Product granted to Novartis hereunder shall automatically terminate and revert to Regeneron, on a country-by-country basis, if applicable.

(b) Upon termination of this Agreement by Novartis pursuant to Section 19.5, 19.6 or 19.7(a), the provisions of Part B of SCHEDULE 19 (other than, with respect to any termination under Section 19.7(a), paragraph 2(a) of Part B of SCHEDULE 19) shall apply with respect to the each terminated IL-1 Product on a country-by-country basis, if applicable, as if the terminated IL-1 Product is a "Terminated Product", and except to the extent required by Regeneron to fulfill its obligations pursuant to Part B of SCHEDULE 19 (and upon the earlier of such fulfillment or written notice from Novartis that is will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Novartis), all licenses and rights with respect to the terminated IL-1 Product granted to Regeneron hereunder shall automatically terminate and revert to Novartis, on a country-by-country basis, if applicable.

19.9 Survival of Obligations. Except as otherwise provided in this Article XIX, upon expiration or termination of this Agreement in whole or in part, the rights and obligations of the Parties hereunder shall terminate to the extent of such expiration or termination, and this Agreement shall cease to be of further force or effect to the extent of such expiration or termination, provided that notwithstanding any expiration or termination of

-78-

this Agreement, in whole or in part: (i) neither Novartis nor Regeneron shall be relieved of any obligations of such Party arising prior to such expiration or termination; (ii) subject to the provisions of this Article XIX (including SCHEDULE 19 to the extent applicable), the obligations of the Parties with respect to the protection and nondisclosure of Company Information and New Information in accordance with Article XVI, as well as other provisions (including, without limitation, Article XIX and SCHEDULE 19 to the extent applicable and Sections 5.9 and 6.23) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable, except as set forth in Section 6.22; and (iii) such expiration or termination and this Article XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement, including, without limitation, any breach of the provisions referred to in clause (ii) above.

#### ARTICLE XX

#### MISCELLANEOUS

 $$20.1\ Governing Law.$  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.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding 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 20 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 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 (including Schedules), together with the Stock Purchase Agreement and the Ancillary Agreements (when executed), 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 Novartis and Regeneron.

-79-

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 ("Severed Clause"), then, it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult and use their best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement.

20.8 Registration and Filing of the Agreement. To the extent, if any, that a Party concludes in good faith that it is 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. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. In such situation, the Party making such filing or registration (and the other Party if permitted under applicable Law) will request confidential treatment of sensitive provisions of this Agreement, except to the extent the Party making such request determines in good faith that such confidential treatment is not reasonably likely to be granted under applicable Law. 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 Novartis or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Novartis or (b) the prior written consent of Novartis in the case of an assignment by Regeneron, except in each case to an Affiliate of the assigning Party or, subject to Section 19.7, to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale or 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.

20.11 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.

20.12 Third-Party Beneficiaries. None of the provisions of this Agreement, other than the sublicense to Novartis of rights under the Amgen License Agreement provided for herein (the "Amgen Sublicense"), the penultimate sentence of Section 4.5 and Section 13.4 (collectively, the "Amgen TPB Provisions"), shall be for the benefit of or enforceable by any Third Party including, without limitation, any creditor of any Party hereto. The Parties acknowledge and agree that Amgen (i) shall be a direct Third Party beneficiary of Novartis' obligations under the Amgen TPB Provisions, (ii) may enforce Novartis' obligations under the Amgen TPB Provisions as if it were a party hereto and (iii) shall have the right to seek remedies, including termination of the Amgen Sublicense, in the event Novartis breaches its obligations under the Amgen TPB Provisions. No Third Party (other than Amgen with

-80-

respect to Novartis' obligations under the Amgen TPB Provisions) 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.

20.13 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 except as expressly provided in this Agreement. Neither Novartis 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 or any Ancillary Agreement to the contrary, Regeneron's legal relationship under this Agreement to Novartis, and Novartis' legal relationship under this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.14 Limitation of Damages. IN NO EVENT SHALL REGENERON OR NOVARTIS BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE PAID TO A THIRD PARTY AS PART OF A THIRD-PARTY CLAIM.

20.15 Non-Solicitation. The Parties recognize that each Party has a substantial interest in preserving and maintaining confidential its Company Information and New Information provided to the other Party hereunder. Each Party recognizes that certain of the other Party's employees, including those engaged in the Development, Co-Promotion, Co-Branding or Co-Marketing of IL-1 Products, may have access to such Company Information and New Information of the other Party. The Parties therefore agree, during the Term and for a period of two years thereafter, not to solicit or otherwise induce or attempt to induce for purposes of employment, any employees from the other Party involved in the manufacture, Development, Co-Promotion, Co-Branding or Co-Marketing of any IL-1 Product.

20.16 Hardship. If as a result of unforeseen events or developments relating to the subject matter of this Agreement, the performance of this Agreement shall cause inequitable economic hardship for one Party which runs counter to the objectives of this Agreement and which the other Party cannot reasonably and in good faith expect the first Party to bear unrelieved, the Parties will meet and seek in good faith to find equitable means of amending this Agreement between the Parties hereto.

-81-

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

NOVARTIS PHARMA AG

- By /s/ Subhanu Saxena Name: Subhanu Saxena Title: Head of Global Business Development and Licensing
- By /s/ Kim Urdahl ------Name: Kim Urdahl Title: Head of Legal, Primary Care
- REGENERON PHARMACEUTICALS, INC.
- By /s/ Murray Goldberg

Name: Mr. Murray Goldberg Title: Senior Vice President, Finance and Administration

For the purposes of Section 9.4(a) only:

NOVARTIS PHARMACEUTICALS CORP.

By /s/ Gary Rosenthal Name: Mr. Gary Rosenthal Title: Vice President, Finance and Administration

### Target Profit Splits

Funds flow mechanisms with respect to Co-Commercialization Countries shall be designed to achieve the following Target Profit Splits (for the avoidance of doubt, the Target Profit Splits shall apply independent of the Detailing effort provided by either Party, such that, for example, in the case of the example set forth under paragraph 1 below, in NAFTA if Regeneron provided none of the Detailing efforts, it will still be entitled to 50% of the Net Profits):

1. Trap-1. Net Profits (excluding Development Costs see example below) on sales of the Trap-1 Product in the Co-Commercialization Countries in the Trap-1 Territory to be shared as set forth below:

- (a) NAFTA 50% to Novartis, 50% to Regeneron
- (b) Europe 50% to Novartis, 50% to Regeneron
- (c) Rest of World 75% to Novartis, 25% to Regeneron.

An example of this would be (with respect to, e.g., the United States):

		NVS 50%	RGEN 50%
Net Sales COGS	100.0 (10.0)		
Gross Margin Expenses	90.0 (50.0)	45.0 (25.0)	45.0 (25.0)
Net Profit (Before Dev. Costs) Post-Phase IIB	40.0	20.0	20.0
Development Costs	(10.0)	(5.0)	(5.0)
Net Profit	30.0	15.0	15.0

2. IL-1 Antibody. Net Profits (including Development Costs - see example below) on sales of the IL-1 Antibody Product in the Co-Commercialization Countries in the IL-1 Antibody Territory to be shared 55% to Novartis, 45% to Regeneron. An example of this would be:

100.0 (10.0)		
90.0	49.5	40.5
(50.0)	(27.5)	(22.5)
40.0	22.0	18.0
(10.0)	(5.5)	(4.5)
30.0	16.5	13.5
	(10.0) <u>90.0</u> (50.0) <u>40.0</u> (10.0)	$\begin{array}{c} (10.0) \\ \hline \\ 90.0 \\ 49.5 \\ \hline \\ (50.0) \\ \hline \\ 40.0 \\ 22.0 \\ \hline \\ (10.0) \\ \hline \\ 30.0 \\ 16.5 \\ \hline \end{array}$

Schedule 1 Page 2

3. Trap-2. Net Profits (including Development Costs - see example below) on sales of the Trap-2 Product in the Co-Commercialization Countries in the Trap-2 Territory to be shared as set forth below:

- (a) NAFTA 50% to Novartis, 50% to Regeneron
- (b) Europe 50% to Novartis, 50% to Regeneron
- (c) Rest of World 75% to Novartis, 25% to Regeneron.

An example of this would be (with respect to, e.g., the United States):

		NVS 50%	RGEN 50%
Net Sales COGS	100.0 (10.0)		
Gross Margin Expenses	90.0 (50.0)	45.0 (25.0)	45.0 (25.0)
Net Profit (Before Dev. Costs) Post-Phase IIB	40.0	20.0	20.0
Development Costs	(10.0)	( 5.0)	( 5.0)
Net Profit	30.0	15.0	15.0

# Proportion of Detailing Efforts

# (See Section 6.10(a))

# 1. Trap-1.

	Novartis	Regeneron
Region	Percentage	Percentage
NAFTA	[****]	[*****]
Europe	[****]	[****]
Rest of World	[****]	[****]

2. IL-1 Antibody.

	Novartis	Regeneron
Region	Percentage	Percentage
NAFTA	[****]	[*****]

# 3. Trap-2.

	Novartis	Regeneron
Region	Percentage	Percentage
NAFTA	[****]	[****]
Europe	[****]	[****]
Rest of World	[****]	[****]

SCHEDULE 3

## Royalty

(see Section 9.3)

# Shared Development Costs

# (see Section 9.2(a))

1. Trap-1.

(a) Commencing in 2004, Novartis will be responsible for one hundred percent (100%) of aggregate Pre-Phase III Development Costs for the Trap-1 Product in the Co-Commercialization Countries in the Trap-1 Territory.

(b) Other than as set forth in paragraph (a) above, the Parties will each be responsible for fifty percent (50%) of the aggregate Development Costs for the Trap-1 Product in the Co-Commercialization Countries in the Trap-1 Territory.

(c) In the event that a Party has incurred less than its applicable percentage share of such Development Costs for an applicable calendar quarter, then, pursuant to Section 9.2(a) such Party shall reimburse the other Party in such amount as is necessary to result in each Party bearing its applicable share of such Development Costs for such calendar quarter.

(d) For avoidance of doubt, commencing in 2004, if there are Phase II Development Costs for the Trap-1 Product at the same time that there are Phase III Development Costs for the Trap-1 Product, Novartis will be responsible for 100% of the Phase II Development Costs and the Parties will share equally in the Phase III Development Costs.

2. IL-1 Antibody. Novartis shall be responsible for an amount equal to the product of the aggregate Development Costs for the IL-1 Antibody Product in the Co-Commercialization Countries for NAFTA for the relevant calendar quarter multiplied by fifty-five percent (55%), and Regeneron shall be responsible for an amount equal to the product of the aggregate Development Costs for the IL-1 Antibody Product in the Co-Commercialization Countries in NAFTA for the relevant calendar quarter multiplied by forty-five percent (45%). In the event that a Party has incurred less than its applicable percentage share of such Development Costs for an applicable calendar quarter, then, pursuant to Section 9.2(a), such Party shall reimburse the other Party in such amount as is necessary to result in each Party bearing its applicable share of such Development Costs for such calendar quarter.

3. Trap-2. The Parties will each be responsible for fifty percent (50%) of the aggregate Development Costs for the Trap-2 Product in the Co-Commercialization Countries in the Trap-2 Territory. In the event that a Party has incurred less than its applicable percentage share of such Development Costs for an applicable calendar quarter, then, pursuant to Section 9.2(a), such Party shall reimburse the other Party in such amount as is necessary to result in each Party bearing its applicable share of such Development Costs for such calendar quarter.

## Failure to Perform Details

## (see Section 6.10 (e))

If a Party fails to actually perform committed Details, then the penalty will be calculated as a multiple of the costs associated with the missed details. The multiplying factor is calculated as follows:

The Party which has failed to perform committed Details will have the opportunity to cure the shortfall in the next quarter and thereby avoid or reduce, as applicable, the penalty that would otherwise apply.

## Milestone Payments

## (see Section 9.4(b))

## 1. Trap-1.

Upon the first occurrence of each of the events set forth below, Novartis shall pay to Regeneron the corresponding amount set forth below:

	Milestone
Milestone Event	Payment
[**************************************	[*******]
[******	[*******]
[**************************************	[*********]
[**************************************	[*********]

For the avoidance of doubt, each of the above milestones will be payable only once, but may occur in the same year.

## 2. IL-1 Antibody.

Upon the first occurrence of each of the events set forth below, Regeneron shall pay to Novartis the corresponding amount set forth below:

	Milestone
Milestone Event	Payment
[******	[******]
[******	[*******]
[******	[*******]

For the avoidance of doubt, each of the above milestones will be payable only once, but may occur in the same year.

3. Trap-2.

Upon the first occurrence of each of the events set forth below, Novartis shall pay to Regeneron the corresponding amount set forth below:

	Milestone
Milestone Event	Payment
[**************************************	[*********]

[************************]	[**********]
[************************]	[*********]

For the avoidance of doubt, each of the above milestones will be payable only once, but may occur in the same year.

PRINCIPLES IN DETERMINING COGS:

(SEE SECTION 8.2(a))

Non-binding example of the cost pricing details for the processing of Trap-1

## Preliminary Development Plan

## IL-1 TRAP PRELIMINARY DEVELOPMENT PLAN

[***********	* * * * * * * * * * * * * * * * * * * *	*******
**********	* * * * * * * * * * * * * * * * * * * *	*******
***********	***************************************	*******
******	********	*******]

## (\$ IN MM)

[\* \* \* \* \* \* \*]

IL-1 TRAP - R&D SUPPORT - PRELIMINARY OUTSIDE EXPENSES

(\$ IN MM)

[\* \* \* \* \* \* \*]

# Non-Distributor Countries

# (See Sections 4.1, 4.3 and 6.1)

[\*]

SCHEDULE 11

Regulatory Tasks To Be Conducted By Novartis in U.S. For Trap-1 and Trap-2  $\,$ 

(See Sections 7.1 and 7.6)

Preparation and formatting of the BLA via electronic submission

Provision of electronic study templates and documents

Quality check on all documents/data for submission

Quality check on datasets prior to final study report

Coordination of pharmacoviligance activities and submission of reports via electronic submission, if possible

Procedures for Adverse Event and Other Safety Data Exchange Notification and Reporting [TO BE ADDED.] SCHEDULE 13

Existing Licenses

[INTENTIONALLY OMITTED]

#### Transition Arrangements

The rights and obligations set forth in this SCHEDULE 19 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the Terminated Product(s) as to which, in the countries in which, the Agreement has been terminated.

#### PART A - TRANSITION TO REGENERON

1. Novartis 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 provided by Regeneron and containing Company Information or New Information of Regeneron relating to the Terminated Product(s) in any countries in which the Agreement has been terminated, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any such Company Information or New Information of Regeneron with respect to the Terminated Products in any countries in which the Agreement has been terminated;

2. Novartis 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 and/or Commercialization of Terminated Product(s) in all countries in which the Agreement has been terminated. 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 have an exclusive license (which shall include the right to grant sublicenses) from Novartis under Novartis Patent Rights and Novartis Know-How existing at the effective date of termination to Develop, make, have made, use, import, offer to sell and sell the Terminated Products in the applicable countries. Such license shall be fully paid-up and royalty-free if the Terminated Product is the Trap-1 Product or the Trap-2 Product, and, if the Terminated Product is the IL-1 Antibody Product, such license shall be subject to a royalty unless the Agreement was terminated with respect to the IL-1 Antibody Product by Regeneron pursuant to Section 19.4. The amount of such royalty shall be determined by the mutual agreement of the Parties after good faith negotiations and shall be dependent upon (i) the stage of Development and/or Commercialization of the Terminated Product(s); (ii) the anticipated future profitability of the Terminated Product(s). If the Parties are unable to reach mutual agreement thereon within three (3) months after the effective date of termination, the matter shall be submitted for arbitration in accordance with the terms of Article X of this Agreement.

(b) Novartis shall transfer and assign to Regeneron (or its nominee) all Approvals and regulatory filings (including Registration Filings) in the applicable countries made or obtained by Novartis or its Affiliates or any of its sublicensees to the extent relating to Terminated Product(s) (other than Approvals for manufacturing facilities). (c) Novartis shall assign and transfer to Regeneron (or its nominee) Novartis' entire right, title and interest in and to all Product Trademarks to the extent relating to Terminated Product(s) in the applicable countries and to any domain names containing such Product Trademarks.

(d) Novartis shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the manufacture, Development or Commercialization of Terminated Product(s) in all countries in which the Agreement has been terminated of all information (including any Novartis Company Information and/or New Information) in its possession or under its control to the extent relating to any Terminated Product(s) in all countries in which the Agreement has been terminated, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Novartis, or such other format as may be reasonably requested by Regeneron and notwithstanding any provision of Article XVI, Regeneron shall be entitled to use and disclose any such information (including any such Novartis Company Information and/or New Information, production of any Terminated Product(s) in the applicable countries.

(e) To the extent the Terminated Product is being manufactured by a Third Party as of the date notice of termination is given, then Novartis shall assign to Regeneron Novartis' rights with respect to the Terminated Product under its agreement with the Third Party manufacturer in so far as they relate to any country which is the subject of the termination.

(f) Novartis shall assign to Regeneron any applicable sublicenses to the extent related to Terminated Products and/or subcontracts relating to significant services to be performed by Third Parties to the extent related to manufacture, Development or Commercialization of Terminated Products in the applicable countries, as reasonably requested by Regeneron.

(g) Without limitation of Novartis' other rights obligations under this Part A of SCHEDULE 19, (i) In the event that Novartis or any of its Affiliates is responsible for manufacturing any Terminated Product as of the date notice of termination is given, Novartis will take the actions required by subparagraph (g) (ii) below, including, for a period and at the price described in paragraph (g) (ii) below, supplying Regeneron with Clinical Supply Requirements and/or Commercial Requirements, as applicable.

(ii) (A) In the event notice of termination is given prior to Launch of the Terminated Product(s) and Novartis's manufacturing facility or facilities to manufacture such Terminated Product which is referred to in Section 8.2(a) of the Agreement (the "Novartis' Manufacturing Facilities") has (have) not yet been completed, Novartis will use Commercially Reasonable Efforts to complete the construction and build-out of the Novartis Manufacturing Facilities as expeditiously as possible, and will supply Regeneron with Clinical Supply Requirements and/or Commercial Requirements, as applicable, of finished and packaged Terminated Product(s) for use in any country which is the subject of the termination, at the same price, and on such other terms and conditions on, which Novartis was supplying, or in the absence of termination, would have been required to supply such finished and packaged Terminated Product(s), through the second anniversary of the Launch of such Terminated  $\mbox{Product}(s)$  .

(B) In the event notice of termination is given prior to Launch of the Terminated Product(s) and the Novartis Manufacturing Facilities have been completed, Novartis will supply Regeneron with Clinical Supply Requirements and/or Commercial Requirements, as applicable, of finished and packaged Terminated Products for use in any country which is the subject of the termination on the same price and other terms and conditions, and for the same period as provided in subparagraph (ii) (A) above.

(C) In the event notice of termination is given after Launch of the Terminated Product(s), Novartis will supply Regeneron with Commercial Requirements of finished and packaged Terminated Product(s) for use in any country which is the subject of the termination at same price and other terms and conditions as provided in subparagraph (ii) (A) above, until the second anniversary of the effective date of termination, and if Regeneron so requests, for one additional year, provided that the price and other terms and conditions on, which such Terminated Products will be supplied for such additional year shall be reasonable and customary as determined by good faith negotiations between the Parties.

3. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the manufacture, Co-Development and Co-Commercialization of any Terminated Products hereunder to Development, Commercialization of such Terminated Products for use in any country which is the subject of the termination solely by Regeneron or its designees as soon as is reasonably possible.

4. For the avoidance of doubt, except as set forth in paragraph 2(a) above, Regeneron shall not be required to provide Novartis any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Part A of SCHEDULE 19; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Novartis 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.

PART B - TRANSITION TO NOVARTIS

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Novartis or, at Novartis' request, destroy, all documents provided by Novartis and containing Company Information or New Information of Novartis relating to the Terminated Product(s) in any countries in which the Agreement has been terminated, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any such Company Information or New Information of Novartis with respect to the Terminated Product(s) in any countries in which the Agreement has been terminated;

2. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Novartis to enable Novartis (or its nominee) to assume with as little disruption as reasonably possible, the continued Development and/or Commercialization of Terminated Product(s) in all countries in which the Agreement has been terminated. 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) Novartis shall have an exclusive license (which shall include the right to grant sublicenses) from Regeneron under Regeneron Patent Rights and Regeneron Know-How existing at the effective date of termination to Develop, make, have made, use, import, offer to sell and sell the Terminated Products in the applicable countries. Such license shall be fully paid-up and royalty-free if the Terminated Product is the IL-1 Antibody Product, and, if the Terminated Product is the Trap-1 Product or the Trap-2 Product, such license shall be subject to a royalty, unless the Agreement was terminated with respect to the Trap-1 Product or Trap-2 Product, as applicable, by Novartis pursuant to Section 19.4. The amount of such royalty shall be determined by the mutual agreement of the Parties after good faith negotiations and shall be dependent upon (i) the stage of Development and/or Commercialization of the Terminated Product(s); (ii) the anticipated future profitability of the Terminated Product(s) and (iii) the efforts and expenses to be incurred by the terminating Party in Developing and Commercializing the Terminated Product(s). If the Parties are unable to reach mutual agreement thereon within three (3) months after the effective date of termination, the matter shall be submitted for arbitration in accordance with the terms of Article X of this Agreement.

(b) Regeneron shall transfer and assign to Novartis (or its nominee) all Approvals and regulatory filings (including Registration Filings) in the applicable countries made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent relating to Terminated Product(s) (other than Approvals for manufacturing facilities).

(c) Regeneron shall assign and transfer to Novartis (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks to the extent relating to Terminated Product(s) in the applicable countries, and to any domain names containing such Product Trademarks.

(d) Regeneron shall provide to Novartis (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the manufacture, Development or Commercialization of Terminated Product(s) of all information (including any Regeneron Company Information and/or New Information) in its possession or under its control to the extent relating to any Terminated Product(s) in all countries in which the Agreement has been terminated, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, and notwithstanding any provision of Article XVI, Novartis shall be entitled to use and disclose any such information (including any such Regeneron Company Information and/or New Information) in connection with the manufacture, Development or Commercialization of any Terminated Product(s) in the applicable countries.

(e) To the extent Terminated Product is being manufactured by a Third Party under contract with or from Regeneron as of the date notice of termination is given, then Regeneron shall assign to Novartis Regeneron's rights with respect to the Terminated Product under such agreement with the Third Party manufacturer as far as they relate to any country which is the subject of the termination. Schedule 19 Page 5

(f) Regeneron shall assign to Novartis any applicable sublicenses to the extent related to Terminated Products and/or subcontracts relating to significant services to be performed by Third Parties to the extent related to manufacture, Development or Commercialization of Terminated Products in the applicable countries, as reasonably requested by Novartis.

(g) In the event that Regeneron or any of its Affiliates is responsible for manufacturing any Terminated Product as of the date of termination, Regeneron will, for a period not to exceed two (2) years following such date, supply Novartis with sufficient quantities of such Terminated Product to enable Novartis to continue the Development of such Terminated Product in accordance with the scope of the Consolidated Co-Development Plan as at the date of such termination. Regeneron shall supply such Terminated Product to Novartis and its Affiliates at the same price, and on such other terms and conditions on, which Regeneron was supplying such Terminated Product pursuant to this Agreement.

3. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the manufacture, Co-Development and Co-Commercialization of any Terminated Products hereunder to manufacture, Development and Commercialization solely by Novartis, its Affiliates and/or designees as soon as is reasonably possible.

4. For the avoidance of doubt, except as set forth in paragraph 2(a) above, Novartis 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 Part B of SCHEDULE 19; provided, however, that Novartis 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 Novartis of such licenses or other rights.

# NOTICES

(a) If to Novartis:

Novartis Pharma AG CH-4002 Basel, Switzerland Attention: Head of Business Development & Licensing Copy: Head of Legal Services

(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

# Exhibit 10.24

-----

STOCK PURCHASE AGREEMENT

By and Between

NOVARTIS PHARMA AG

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of March 28, 2003

#### STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT ("Agreement"), dated as of March 28, 2003, by and between NOVARTIS PHARMA AG (the "Investor"), a corporation organized under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, 4056 Basel, Switzerland, and REGENERON PHARMACEUTICALS, INC. (the "Company"), a corporation organized under the laws of New York with its principal place of business at 777 Old Saw Mill Road, Tarrytown, New York, U.S.A.

WHEREAS, concurrently with the execution of this Agreement, the Investor and the Company have entered into a Collaboration, License and Option Agreement (the "Collaboration Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement, and together with the Collaboration Agreement, the "Transaction Agreements"); and

WHEREAS, it is contemplated by the Collaboration Agreement that the Investor purchases, and the Company issues and sells to the Investor, shares of common stock of the Company pursuant to the terms and conditions of this Agreement.

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

#### ARTICLE I

#### DEFINITIONS

Section 1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"Adjustment Period Termination Date" shall mean the thirtieth trading day immediately succeeding the date hereof.

"Business Day" shall mean any day other than a Saturday or Sunday or a day on which banks located in New York, New York or Basel, Switzerland are authorized or required by law to close.

"Draft Form 10-K" shall mean the draft of the Company's Form 10-K, dated March 4, 2003, for the year ended December 31, 2002, provided to the Investor by the Company as amended by the substitution of page 14 thereof by a document delivered to the Investor on March 26, 2003.

"Governmental Authority" shall mean any federal, state, municipal, local, provincial, regional governmental authority in the United States or other political subdivision thereof and any Person exercising executive, legislative, judicial regulatory or administrative functions of or pertaining to government. "Material Adverse Effect" shall mean any events, occurrences or circumstances which give rise to or would reasonably be expected to give rise to, individually or in the aggregate, a material adverse effect on (i) the business, properties, financial condition or results of operations of the Company, or (ii) the ability of the Company to comply with its obligations under the Transaction Agreements.

"Per Share Price" shall mean the average closing price per share of the Company's common stock as quoted in the Wall Street Journal on each trading day during the period commencing on the eleventh trading day immediately succeeding the date hereof and ending on (and including) the Adjustment Period Termination Date.

"Person" shall mean and include an individual, a partnership, a joint venture, a corporation, a limited liability company, a limited liability partnership, a trust, an incorporated organization and a Governmental Authority.

Section 1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

	Defined Term	Section	Defined Term	Section
ANDA Axok BLA Clos Clos Coll Comp Comp	eement ine Press Release ing ing Date Stock aboration Agreement	Preamble 3.16(a) 6.13(b) 3.16(a) 2.2 2.1 Preamble Preamble 3.14(a)(ii) 3.11 3.16(b)	Indemnified Parties Indemnifying Party Intellectual Property IND Investor NDA Organizational Documents Purchase Price Purchased Stock Registration Rights Agreement Securities Act Severed Clause	6.2 6.2 3.14 (a) (i) 3.16 (a) Preamble 3.16 (a) 3.1 2.1 2.4 (a) Preamble 3.2 (b) 6.12
GLP		3.16(c)	Transaction Agreements	Preamble

Section 1.3 Construction. In this Agreement, unless the context otherwise requires:

 (a) any reference in this Agreement to "writing" or comparable expressions includes a reference to facsimile transmission or comparable means of communication;

(b) words expressed in the singular number shall include the plural and vice versa, words expressed in the masculine shall include the feminine and neuter gender and vice versa;

(c) references to Articles and Sections are references to articles and sections of this Agreement; (e) this "Agreement" or any other agreement or document shall be construed as a reference to this Agreement or, as the case may be, such other agreement or document as the same may have been, or may from time to time be, amended, varied, novated or supplemented; and

(f) "include," "includes," and "including" are deemed to be followed by "without limitation" whether or not they are in fact followed by such words or words of similar import.

Section 1.4 Knowledge. Where any representation or warranty contained in this Agreement is expressly qualified by reference to the knowledge of the Company, the Company confirms that it has made due and diligent inquiry as to the matters that are the subject of such representations and warranty.

#### ARTICLE II

#### PURCHASE AND SALE OF COMMON STOCK

Section 2.1 Issuance of Common Stock. Subject to the terms and conditions hereof, on the date hereof, the Company agrees to issue and sell to the Investor, and the Investor agrees to purchase, 2,400,000 shares of its common stock (the "Closing Date Stock") for an aggregate purchase price of \$48,000,000 (the "Purchase Price"), such number of shares of its common stock to be adjusted pursuant to Section 2.4

Section 2.2 Closing. The purchase and sale of the Purchased Stock (the "Closing") shall occur on the date hereof at the Company's offices at 777 Old Saw Mill Road, Tarrytown, New York.

Section 2.3 Delivery. The Company shall deliver to the Investor a stock certificate, registered in the Investor's name, representing the Purchased Stock, against payment of the Purchase Price by certified or cashier's check payable to the Company, or by wire transfer of same day funds to the Company's bank account as follows:

Beneficiary Name:	[*			
Beneficiary Address:	[*	*	*	*]
Account Number:	[*			
Bank Name:	[*			
Bank Address:	[*	*	*	*]
Bank Clearing Number:	[*	*	*	*]

Section 2.4 Determination of Purchased Stock.

(a) In the event that the number of shares of common stock of the Company which is equal to the nearest whole number that is obtained by dividing \$48,000,000 by the Per Share Price is (x) less than the number of shares of Closing Date Stock, the Investor shall promptly, but in no event later than the thirty-fifth trading day immediately succeeding the date hereof, deliver to the Company an amount of shares of common stock of the Company that is equal to such deficiency, or (y) greater than the number of shares of Closing Date Stock, the Company shall promptly, but in no event later than the thirty-fifth trading day immediately succeeding the date hereof, issue and deliver to the Investor, an amount of shares of common stock of the Company that is equal to such excess, provided, however that the aggregate amount of the Company's common stock issued to the Investor pursuant to Section 2.1 and this subsection (y) shall in no event exceed 19.9% of the issued and outstanding common stock of the Company as of the date hereof. The Closing Date Stock, as adjusted pursuant to this Section 2.4, is referred to herein as the "Purchased Stock").

(b) For the purposes of determining the number of shares of Purchased Stock required to be delivered pursuant to Section 2.4(a), adjustment shall be made in the event of any stock split, stock dividend, reverse stock split, recepitalization or the like that occurs between the Closing and the Adjustment Period Termination Date.

# ARTICLE III

#### REPRESENTATIONS AND WARRANTIES OF THE COMPANY

## The Company hereby represents and warrants to the Investor as

follows:

Section 3.1 Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. The Company has all requisite corporate power and corporate authority to own and operate its properties and assets, to carry on its business as now conducted, to enter into the Transaction Agreements, to issue and sell the Purchased Stock and to carry out the other transactions contemplated under the Transaction Agreements. The Company is qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by the Company or the nature of the business conducted by the Company makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect. The Company has delivered to the Investor true, correct and complete copies of the Company's Restated Certificate of Incorporation and the Company's By-laws (together, the "Organizational

Section 3.2 Capitalization and Voting Rights.

(a) The authorized capital of the Company as of March 26, 2003 consists of: (i) 160,000,000 shares of common stock, par value 0.001 per share, of which (x) 42,021,013 shares are issued and outstanding, (y) 2,486,181 shares are reserved for issuance upon conversion of the class A common stock, each share of class A common stock being convertible into one share of common stock, and (z) 11,401,366 shares are reserved for issuance pursuant to the Company's 1990 Long-Term Incentive Plan and 2000 Long-Term Incentive Plan, (ii) 40,000,000 shares of class A common stock, par value 0.001 per share, of which 2,486,181

Documents") as in effect on the date hereof.

shares are issued and outstanding, and (iii) 30,000,000 shares of preferred stock, par value \$0.01 per share, of which no shares are issued and outstanding. All of the issued and outstanding shares of common stock and class A common stock have been duly authorized, and all of the issued and outstanding shares of common stock and class A common stock have been validly issued, are fully paid and non-assessable, and were issued in compliance with all applicable federal and state securities laws.

(b) Except as set forth in the Company SEC Documents filed prior to the date of this Agreement or in the Draft Form 10-K, or as provided in the Transaction Agreements, there are not, nor upon the consummation of the transactions contemplated hereby, shall there be: (i) any outstanding options, warrants, rights (including conversion or preemptive rights) or agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company; (ii) any restrictions on the transfer of capital stock of the Company is a party, any order of any court or any Governmental Authority to which the Company is subject, or any law other than state and federal securities laws; and (iii) any registration rights (including piggy-back rights) under the Securities Act of 1933, as amended (the "Securities Act") with respect to shares of the Company's capital stock.

(c) Except as set forth in the Company SEC Documents filed prior to the date of this Agreement or in the Draft Form 10-K, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a shareholder or director of the Company.

(d) Since December 31, 2002, the Company has only issued stock options to its or subsidiaries' employees in the ordinary course of business, consistent with past practice.

Section 3.3 Subsidiaries. The Company does not have any subsidiaries required to be disclosed in Exhibit 21 to the Draft Form 10-K.

Section 3.4 Authorization. All corporate action on the part of the Company, its directors and stockholders necessary for the authorization, execution and delivery of the Transaction Agreements, the performance of all obligations of the Company thereunder, including the authorization, issuance and delivery of the Purchased Stock, has been taken. The Transaction Agreements have been duly executed and delivered by the Company and constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application relating to or affecting enforcement of creditors' rights).

Section 3.5 No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Company, does not and shall not: (a) violate any provision of law, statute, ordinance, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any Governmental Authority, (b) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute (whether or not with due notice or lapse of time, or both) a default (or give rise to any right of termination, cancellation or acceleration) or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Company pursuant to any agreement, document, instrument, contract, understanding, arrangement, note, indenture, mortgage, lease or permit to which the Company is a party, or under which the Company or any of its assets is bound or affected, or (c) violate or conflict with any of the provisions of the Organizational Documents; except, in the case of subsections (a) and (b) as would not have a Material Adverse Effect.

Section 3.6 Valid Issuance of Purchased Stock. When issued, sold and delivered in accordance with the terms hereof for the consideration expressed herein, the Purchased Stock shall be validly issued and outstanding, fully paid and nonassessable, free from any encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than restrictions on transfer under the Transaction Agreements and under federal and state securities laws.

Section 3.7 Governmental Consents. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority is required in connection with the consummation of the transactions contemplated by the Transaction Agreements, except for registration or qualification, or taking such action to secure exemption from such registration or qualification, of the Purchased Stock under applicable state or federal securities laws, which actions shall be taken, by and at the expense of the Company, on a timely basis as may be required.

Section 3.8 Litigation. Except as set forth in the Company SEC Documents filed prior to the date of this Agreement or in the Draft Form 10-K, there is no action, suit, proceeding or investigation pending or threatened against the Company or which the Company intends to initiate which questions the validity of the Transaction Agreements or the right of the Company to enter into them, or to consummate the transactions contemplated thereby, or which have a Material Adverse Effect, or result in any material change in the current equity ownership of the Company.

Section 3.9 Licenses and Other Rights; Compliance with Laws. The Company has all franchises, permits, licenses and other rights and privileges necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder except where the failure to be in compliance does not have a Material Adverse Effect. The Company is and has been in compliance with all laws and governmental rules and regulations applicable to its business, properties and assets, and to the products and services sold by it, including, without limitation, all such rules, laws and regulations relating to fair employment practices, occupational safety and health and public safety, except where the failure to be in compliance does not have a Material Adverse Effect.

Section 3.10 Compliance with Other Instruments; Action. The Company has neither received written notice nor otherwise has knowledge of any violation or default of (a) any of the terms, conditions or provisions of any agreement, document, instrument, contract, understanding, arrangement, note, indenture, mortgage, lease or permit to which the Company is a party, or under which the Company or any of its assets is bound or affected, or (b) the Organizational Documents; except, in the case of subsection (a) as would not have a Material Adverse Effect.

Section 3.11 Company SEC Documents; Financial Statements.

(a) Since December 31, 2001, the Company has filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) with the SEC ("Company SEC Documents"). As of their respective dates, each of the Company SEC Documents complied, and the Draft Form 10-K complies, in all material respects with the requirements of the Securities Act or the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents and the Draft Form 10-K, and no Company SEC Documents when filed contained, and the Draft Form 10-K does not contain, any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The financial statements of the Company included in the Draft Form 10-K comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present the financial position of the company as of the dates thereof and the results of its operations and cash flows for the periods then ended.

Section 3.12 Liabilities. The Company does not have any liabilities, whether absolute, accrued, contingent or otherwise, except for liabilities (i) set forth in the audited balance sheet for the year ended December 31, 2002 included in the Draft Form 10-K, or specifically disclosed in the footnotes thereto or (ii) incurred in the ordinary course of business since December 31, 2002, that do not have a Material Adverse Effect.

Section 3.13 Absence of Changes. Since December 31, 2002, there has not been a Material Adverse Effect.

Section 3.14 Intellectual Property.

(a) For purposes of this Agreement, (i) "Intellectual Property" shall mean any of the following: (u) patents and patent applications; (v) registered and unregistered trademarks, service marks and other indicia of origin, pending trademark and service mark registration applications, and intent-to-use registrations or similar reservations of marks; (w) registered and unregistered copyrights and applications therefor; (x) internet domain names, applications and reservations therefor; uniform resource locators and the corresponding Internet sites; (y) trade secrets and proprietary information not otherwise listed in (u) through (x) above, including, without limitation, unpatented inventions, invention disclosures, confidential information, technical data, customer lists, corporate and business names, trade names, trade dress, brand names, know-how, formulae, methods (whether or not patentable), designs, processes, procedures, technology, source codes, object codes, computer software programs, databases, data collections and other proprietary information or material of any type, and all derivatives, improvements and refinements thereof, howsoever recorded, or unrecorded; and (6) any good will associated with any of the foregoing; and (ii) "Company Intellectual Property" shall mean any Intellectual Property or rights thereto, owned by or licensed to the Company for use in connection with the business of the Company.

(b) Except as does not have a Material Adverse Effect, except as set forth in the Company SEC Documents filed prior to the date of this Agreement or in the Draft Form 10-K, and except with respect to the Trap-1 (as such term is defined in the Collaboration Agreement):

(i) each item of Company Intellectual Property which is registered, filed, issued or applied for, has been duly and validly registered in, filed in or issued by, the official governmental registrars and/or issuers (or officially recognized issuers) of patents, trademarks, copyrights or Internet domain names, in their respective jurisdictions of use and intended use, and each such registration, filing and/or issuance (x) has not been abandoned, canceled or otherwise compromised, (y) has been maintained effective by all requisite filings, renewals and payments, and (z) remains in full force and effect;

the Company has the exclusive right to file, prosecute and maintain all applications and registrations with respect to the Company Intellectual Property;

(iii) the Company owns or is licensed to use the Company Intellectual Property free and clear of any Liens, other than Permitted Liens without, with respect to Company-owned Intellectual Property, obligation to pay any royalty or any other fees with respect thereto; and

(iv) the Company has not received any notice of any claim, or a threat of any claim, from any third party, and no third party claims are pending, (i) challenging the right of the Company to use any Intellectual Property or alleging any violation, infringement, misuse or misappropriation by the Company of any Intellectual Property or indicating that the failure to take a license would result in any such claim, or (ii) challenging the ownership rights of the Company in any Company Intellectual Property or asserting any opposition, interference, invalidity, termination, abandonment, unenforceability, or other infirmity of any Company Intellectual Property.

Section 3.15 Environmental Matters.

(a) For purposes of this Agreement:

(i) "Environmental Claim" means any claim, action, cause of action, investigation or written notice by any person or entity alleging potential liability (including, without limitation, potential liability for investigatory costs, cleanup costs, governmental response costs, natural resources damages, property damages, personal injuries, or penalties) arising out of, based on or resulting from (a) the presence or Release of any Hazardous Materials at any location, whether or not owned or operated by the Company, or (b) circumstances forming the basis of any violation of any Environmental Law. (ii) "Environmental Laws" means all federal, state, local and foreign laws and regulations relating to pollution or protection of human health or the environment, including without limitation, laws relating to Releases or threatened Releases of Hazardous Materials or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, transport or handling of Hazardous Materials.

(iii) "Hazardous Materials" means all substances defined as Hazardous Substances, Oils, Pollutants or Contaminants in the Natural Oil and Hazardous Substances Pollution Contingency Plan, 40 C.F.R. Section 300.5, or defined as such by, or regulated as such under, any Environmental Law.

(iv) "Release" means any release, spill, emission, discharge, leaking, pumping, injection, deposit, disposal, dispersal, leaching or migration into the environment (including, without limitation, ambient air, surface water, groundwater and surface or subsurface strata) or into or out of any property, including the movement of Hazardous Materials through or in the air, soil, surface water, groundwater or property.

(b) Except as set forth in the Company SEC Documents and the Draft Form 10-K:

(i) the Company is in compliance with all applicable Environmental Laws (which compliance includes, but is not limited to, the possession by the Company of all permits and other governmental authorizations required under applicable Environmental Laws, and compliance with the terms and conditions thereof), except where failure to so comply would not have a Material Adverse Effect; and

(ii) there is no Environmental Claim pending or threatened against the Company which would have a Material Adverse Effect

Section 3.16 FDA Matters.

(a) No director, officer or, to the Company's knowledge, employee of the Company directly involved in clinical trials has ever been convicted of a felony under law for conduct relating to the development, testing or approval of any drug, biological product or device, or the preparation or submission of an Investigational New Drug Application ("IND"), a New Drug Application ("NDA"), an Abbreviated New Drug Application ("ANDA"), or a Biologics License Application ("BLA").

(b) All clinical trials conducted, supervised or monitored by or on behalf of the Company have been conducted in compliance with all applicable federal, state and local laws, regulations, rules and requirements, including, but not limited to, current Good Clinical Practices ("GCPs") and the requirements of the regulations of the Food and Drug Administration ("FDA") at, where applicable, 21 C.F.R. Part 312, and 21 C.F.R. Part 50, and the Company has not been cited for failure to comply with GCPs, except where any failure to so comply would not have a Material Adverse Effect. (c) All nonclinical studies conducted by or on behalf of the Company are and have been conducted in accordance with current Good Laboratory Practices ("GLPs") and the requirements of the regulations of the FDA at, where applicable, in 21 C.F.R. Part 58, and the Company has not been cited for failure to comply with GLPs, except where the failure to so conduct such studies or to so comply would not have a Material Adverse Effect.

(d) Neither the Company nor, to the Company's knowledge, any of its agents or employees directly involved in clinical trials have been disqualified or debarred by the FDA under 21 U.S.C. Section 335a, nor has the Company, to its knowledge, used in any capacity the services of any Person who, at the time that the services were rendered, was debarred by the FDA under 21 U.S.C. Section 335a, except where such disqualification or debarrment would not have a Material Adverse Effect.

(e) The Company is in compliance with the applicable provisions, if any, of the Clinical Laboratories Improvement Act of 1967, as amended, except where any failure to so comply would not have a Material Adverse Effect.

Section 3.17 Offering. Subject to the accuracy of the Investor's representations set forth in Section 4.3 and 4.4, the offer, sale and issuance of the Purchased Stock to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements, other than those with which the Company has complied.

Section 3.18 Brokers' or Finders' Fees. No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement.

### ARTICLE IV

# REPRESENTATIONS AND WARRANTIES OF THE INVESTOR

#### The Investor hereby represents and warrants as follows:

Section 4.1 Organization; Good Standing. The Investor is a corporation duly organized, validly existing and in good standing under the laws of Switzerland. The Investor has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to purchase the Purchased Stock and to carry out the other transactions contemplated under the Transaction Documents.

Section 4.2 Authorization. All corporate action on the part of the Investor, and its directors and stockholders necessary for the authorization, execution and delivery of the Transaction Agreements, the performance of all obligations of the Investor thereunder, including the subscription and purchase of the Purchased Stock, has been taken. This Agreement has been duly executed and delivered by the Investor and constitutes a valid and legally binding obligation of the Investor, enforceable against the Investor in accordance with its terms (except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application relating to or affecting enforcement of creditors' rights).

Section 4.3 Purchase Entirely for Own Account. The Purchased Stock shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation, or otherwise distributing the Purchased Stock. The Investor does not have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to such Person any of the Purchased Stock.

Section 4.4 Investment Experience and Accredited Investor Status. The Investor either (i) is an "accredited investor" (as defined in Regulation D under the Securities Act) or (ii) is a "non-U.S. person" (as defined in Regulation S under the Securities Act) and is not acquiring the Purchased Stock for the account or benefit of any U.S. Person.

#### ARTICLE V

## FURTHER ASSURANCES; SECURITIES LAW MATTERS

Section 5.1 Further Assurances. The parties agree to take such reasonable steps and execute such other and further documents as may be necessary or appropriate to cause the terms and conditions contained herein to be carried into effect.

Section 5.2 Restricted Securities. The Investor understands that the Purchased Stock, when issued, shall be restricted securities under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, the Investor represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

Section 5.3 Limitations on Disposition. The Investor shall not make any disposition of all or any portion of the Purchased Stock, except to a subsidiary, unless such disposition is in compliance with Article II of the Registration Rights Agreement and:

 there is then in effect a Registration Statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such Registration Statement;

(b) the disposition is made pursuant to Rule 144 or similar provisions of federal securities laws as in effect from time to time; or

(c) (i) the Investor has notified the Company of the proposed disposition, and (ii) if requested by the Company, the Investor shall have furnished the Company with an opinion of counsel (which counsel shall be reasonably satisfactory to the Company) that such disposition will not require registration of such shares of the Purchased Stock under the Securities Act. The Company agrees and acknowledges that for the purpose of any opinion required pursuant to this

Section 5.3(c), White & Case LLP shall be considered counsel reasonably satisfactory to the Company without any further action or request on the part of the Investor.

Section 5.4 Legends. It is understood that the certificates representing the Purchased Stock shall bear the following legends:

(a) "These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to the Company) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act"; and

(b) any legend required by applicable state securities

# ARTICLE VI

laws.

#### MISCELLANEOUS

## Section 6.1 Survival of Warranties.

(a) Except as set forth in subsection (b) below, the respective representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing until the thirtieth (30th) day after the expiration of the applicable statute of limitations (after giving effect to any waivers and extensions thereto) without regard to any investigation made by any of the parties hereto

(b) The representations and warranties set forth in Section 3.15 (Environmental Matters) shall survive indefinitely without regard to any investigation made by any of the parties hereto.

Section 6.2 Indemnification. Each party (an "Indemnifying Party") shall indemnify, defend and hold the other party and the other party's directors, officers, employees, agents and affiliates (collectively, the "Indemnified Parties") harmless against any and all liabilities, loss, cost or damage, together with all reasonable costs and expenses related thereto (including legal and accounting fees and expenses), arising from, relating to, or connected with the untruth or inaccuracy of any representations or warranties (which untruth or inaccuracy shall, in the case of the representations and warranties set forth in Section 3.15, be determined without regard to any reference to "material" "in all material respects," "Material Adverse Effect" or other materiality qualifier) as of the date hereof, or any breach of any covenants of the Indemnifying Party contained herein. The foregoing indemnification shall survive the termination of this Agreement for any reason.

Section 6.3 Remedies. In case any one or more of the covenants or agreements set forth in this Agreement shall have been breached by any party hereto, the party or parties entitled to the benefit of such covenants or agreements may proceed to protect and enforce their rights either by suit in equity or action at law, including, but not limited to, an action for damages

as a result of any such breach or an action for specific performance of any such covenant or agreement contained in this Agreement. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

Section 6.4 Successors and Assigns. Except as otherwise expressly provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. This Agreement and the rights and duties of the Company set forth herein may not be assigned, in whole or in part, by the Company. The Investor may assign the right and obligation to purchase the Purchased Stock for the Purchase Price, and all of its other rights and obligations under the Transaction Agreements, to any of its subsidiaries, provided that the Investor shall remain liable for the performance of the obligations such subsidiary hereunder and thereunder.

Section 6.5 Entire Agreement. This Agreement (including exhibits hereto), together with the Registration Rights 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. The exhibits to this Agreement are incorporated into and form an integral part hereof. If an exhibit is a form of agreement, such agreement, when executed and delivered by the Parties, shall constitute a document independent of this Agreement.

Section 6.6 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. Each of the parties irrevocably submits to the exclusive jurisdiction of (a) the Supreme Court of the State of New York, and (b) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each of the parties agrees to commence any action, suit or proceeding relating hereto in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional purposes, in the Supreme Court of the State of New York.

Section 6.7 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.

Section 6.8 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

Section 6.9 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth below 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 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.

To the Company:	Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill Road Tarrytown, New York 10591 Attention: General Counsel
With a copy (which shall not constitute notice) to:	Skadden, Arps, Slate, Meagher & Flom LLP 4 Time Square New York, NY 10036 Attention: David J. Goldschmidt, Esq.
To the Investor:	Novartis Pharma AG Lichtstrasse 35 CH-4002 Basel Switzerland Attention: General Counsel
With a copy to (which: shall not constitute notice) to	

Section 6.10 Expenses. Each party shall pay its own fees and expenses with respect to this Agreement. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement or the Articles, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

General Counsel

Section 6.11 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Investor.

Section 6.12 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 ("Severed Clause"), then, it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult and use their reasonable best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement.

# Section 6.13 Confidentiality and Publicity.

(a) Neither the Company nor the Investor shall disclose to any person (other than its attorneys, accountants, employees, officers, and directors) the existence or terms of this Agreement or any of the transactions contemplated hereby without the prior written consent of the other party, except as may, in the reasonable opinion of such party's counsel, be required by law (in which event the disclosing party shall first consult with the other party with respect to such disclosure). If the Company is required to provide a copy of this Agreement or any related document to any third party, the Company shall ensure that such document is redacted, to the extent permitted by law, to eliminate all confidential information. The Investor shall have the right to review and approve each such document prior to its submission to a third party. A period of five (5) Business Days shall be provided for such review unless not permitted by law, in which case the maximum period allowable shall be provided. The Company and the Investor shall consult and reach agreement with one another as to the form and substance of any press release or any other public disclosure of the existence or terms of this Agreement or the transactions contemplated hereby prior to issuing any such press release or making any such public disclosure.

(b) The Company shall not later than April 5, 2003, issue a press release (the "Axokine Press Release") announcing the results of the initial Phase 3 clinical study for Axokine.

[Remainder of page intentionally blank.]

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

NOVARTIS PHARMA AG

By: /s/ Joseph E. Mamie -----Name: Joseph E. Mamie Title: Head Operational Treasury

By: /s/ Kim Urdahl \_\_\_\_\_ Name: Kim Urdahl Title: Head of Legal, Primary Care

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski -----Name: Stuart Kolinski Title: Vice President & General Counsel

# Exhibit 10.25

-----

REGISTRATION RIGHTS AGREEMENT

By and Between

NOVARTIS PHARMA AG

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of March 28, 2003

# REGISTRATION RIGHTS AGREEMENT

THIS REGISTRATION RIGHTS AGREEMENT ("Agreement"), dated as of March 28, 2003, by and between NOVARTIS PHARMA AG (the "Investor"), a corporation organized under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, 4056 Basel, Switzerland, and REGENERON PHARMACEUTICALS, INC. (the "Company"), a corporation organized under the laws of New York with its principal place of business at 777 Old Saw Mill Road, Tarrytown, New York, U.S.A.

## RECITALS

WHEREAS, the Company and the Investor are parties to a Stock Purchase Agreement dated as of the date hereof (the "Stock Purchase Agreement"), pursuant to which the Investor purchased shares of the Company's common stock (the "Purchased Stock").

In consideration of the premises and mutual covenants contained in this Agreement, the parties hereto hereby agree as follows:

# ARTICLE I.

#### REGISTRATION RIGHTS

# Section 1.1 Definitions.

"Affiliate" shall mean, with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with, such Person; provided that, for the purposes of this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), as used with respect to any Person, shall mean the possession, directly or indirectly, of 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.

"Business Day" shall mean any day other than a Saturday or Sunday or a day on which banks located in New York, New York or Basel, Switzerland are authorized or required by law to close.

"Common Stock" shall mean the common stock of the Company, par value  $0.001\ {\rm per}$  share.

"Form S-3" shall mean such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC which permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC.

"Governmental Authority" shall mean any nation or government, any federal, state, municipal, local, provincial, regional or other political subdivision thereof and any Person exercising executive, legislative, judicial regulatory or administrative functions of or pertaining to government.

"Holder" shall mean any Person owning Registrable Securities who is a party to this Agreement or an assignee thereof in accordance with Section 1.11.

"Person" shall mean and include an individual, a partnership, a joint venture, a corporation, a limited liability company, a limited liability partnership, a trust, an incorporated organization and a Governmental Authority.

"Piggy-Back Rights" shall mean the ability of any Person to request or require the inclusion of securities in a registration statement that has been filed, or is proposed to be filed, by the Company for the account of the Investor pursuant to Section 1.4.

"register," "registered," and "registration" refer to a registration effected by preparing and filing a registration statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such registration statement or document.

"Registrable Securities" shall mean (i) the Purchased Stock and any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization, and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Stock, excluding in all cases, however, (x) any Registrable Securities after they have been sold in a transaction in connection with which registration rights granted hereunder are not assigned, or (y) any Registrable Securities sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction, or (z) Registrable Securities eligible for resale pursuant to Rule 144(k) under the Securities Act as provided by, and subject to the other terms of, Section 1.12.

"Registration Expenses" shall mean all expenses incurred by the Company in complying with Sections 1.4 and 1.6 hereof, including, without limitation, all registration and filing fees, fees and expenses of compliance with securities or blue sky laws (including reasonable fees and disbursements of counsel in connection with blue sky qualifications of any Registrable Securities), expenses of printing certificates for any Registrable Securities in a form eligible for deposit with the Depository Trust Company, messenger and delivery expenses, internal expenses (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), and fees and disbursements of counsel for the Company and its independent certified public accountants (including the expenses of any management review, cold comfort letters or any special audits required by or incident to such performance and compliance), Securities Act liability insurance (if the Company elects to obtain such insurance), the reasonable fees and expenses of any special experts retained by the Company in connection with such registration, fees and expenses of other Persons retained by the Company, and, in the case of each of the second (2nd) and fourth (4th) Demand Requests, the reasonable fees and expenses of one (1) counsel for the Holders of Registrable Securities to be

included in the relevant registration, selected by the Holders of a majority of the Registrable Securities to be included in such registration.

"Securities Act" shall mean the Security Act of 1933, as amended from time to time, or any successor statute thereto.

"Securities Exchange Act" shall mean the Security Exchange Act of 1934, as amended from time to time, or any successor thereto.

"Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement.

"SEC" shall mean the U.S. Securities and Exchange Commission.

"Shares of Then Outstanding Capital Stock" shall mean, at any time, the issued and outstanding shares of the Common Stock and Class A Stock of the Company 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 or Class A Stock.

Section 1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section	Defined Term	Section
Acquisition Proposal	2.1(c)	Offered Registrable Securities	2.5
Agreement	Preamble	Permitted Transfer	2.4
Authorization Date	2.5	Required Registration	1.4(a)
Demand Request	1.4(a)	Sale Notice	2.5
Initiating Holders	1.4(b)	Severed Clause	3.10
Lock-Up Period	2.4	Third Party Piggy-Back Request	1.4(c)
Notice Period	2.5	Transfer	2.4
Offeror	2.1(c)	Violation	1.9(a)

Section 1.3 Construction. In this Agreement, unless the context otherwise requires:

 (a) any reference in this Agreement to "writing" or comparable expressions includes a reference to facsimile transmission or comparable means of communication;

(b) words expressed in the singular number shall include the plural and vice versa, words expressed in the masculine shall include the feminine and neuter gender and vice versa;

(c) references to Articles, Sections and Schedules are references to articles, sections and schedules of this Agreement; 3 (e) this "Agreement" or any other agreement or document shall be construed as a reference to this Agreement or, as the case may be, such other agreement or document as the same may have been, or may from time to time be, amended, varied, novated or supplemented; and

(f) "include," "includes," and "including" are deemed to be followed by "without limitation" whether or not they are in fact followed by such words or words of similar import.

Section 1.4 Required Registration. If, at any time after the second anniversary of the date of this Agreement, the Company receives from any Holder or Holders a written request or requests (each, a "Demand Request") that the Company effect a registration (a "Required Registration") under the Securities Act and any related qualification or compliance with respect to shares of Registrable Securities, the Company shall:

 promptly give written notice of the proposed registration, and any related qualification or compliance, to any Holders which did not make such Demand Request; and

(ii) as soon as practicable, effect all such qualifications and compliance as may be so requested and as would permit or facilitate the sale and distribution of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such request, together with all or such portion of the Registrable Securities of any other Holder or Holders joining in such request as are specified in a written request given by such other Holder or Holders within fifteen (15) days after receipt of such written notice from the Company; provided, however, that the Company shall not be obligated to effect any such registration, qualification or compliance, pursuant to this Section 1.4:

(1) if the Company has already completed four (4) Required Registrations;

(2) if the market value of the Registrable Securities proposed to be included in the registration, based on the average closing price during the ten (10) consecutive trading days period prior to the making of the Demand Request, is less than \$10,000,000;

(3) if the Company shall furnish to the Holders a certificate signed by the President and Chief Executive Officer of the Company stating that (i) within sixty (60) days of receipt of the request of the Holder or Holders under this Section 1.4 the Company shall file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (a) issuable pursuant to an employee stock option, stock purchase or similar plan, (b) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act, or (c) in which the only securities which are also being registered), or (ii) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the registration statement, and in the good faith judgment of the Board of Directors of the Company, such disclosure would be seriously detrimental to the Company and its shareholders at such time

(in which case, the Company shall disclose the matter as promptly as reasonably practicable and thereafter file the registration statement and each Holder agrees not to disclose any information about such material transaction to third parties until such disclosure has occurred or such information has entered the public domain other than through breach of this provision by such Holder), provided that the Company shall have the right to only defer the filing of the registration statement pursuant to this subsection, such deferral to be for a period of not more than ninety (90) days after receipt of a Demand Request and provided further, that the Company any only defer the filing of a registration pursuant to this subsection once in any one (1) year period; or

(4) if the Company has, within the six (6) month period preceding the date of the Demand Request, already effected one (1) Required Registration for the Holders pursuant to this Section 1.4.

If the Holders initiating the registration request (b) hereunder (the "Initiating Holders") intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their Demand Request made pursuant to Section 1.4(a) and the Company shall include such information in the written notice referred to in Section 1.4(a)(i). The underwriter shall be selected by a majority in interest of the Initiating Holders and shall be acceptable to the Company. In such event, the right of any Holder to include its Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting (unless otherwise mutually agreed by a majority in interest of the Initiating Holders and such Holder) to the extent such underwriting shall (together with the Company as provided in Section 1.6(h)) enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such underwriting. Notwithstanding any other provision of this Section 1.4, if the managing underwriter determines in good faith that marketing factors require a limitation of the number of shares to be underwritten, then the Company shall so advise all Holders of Registrable Securities which would otherwise be underwritten pursuant hereto, and the number of shares of Registrable Securities that may be included in the underwriting shall be allocated among all Holders thereof, including the Initiating Holders, in proportion (as nearly as practicable) to the amount of Registrable Securities the Company owned by each Holder; provided, however, that the number of shares of Registrable Securities to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting.

(c) Except as set forth on Schedule 1.4(c), the Company represents and warrants to the Investor that as of the date of this Agreement, in the event that any Person is entitled to request (a "Third Party Piggy-Back Request") the inclusion of securities held by it in any Required Registration requested pursuant to this Section 1.4, the terms of the agreement pursuant to which the Company granted such Third Party Piggy-Back Request permit the Company to exclude such securities from the Demand Registration in their entirety in accordance with the provisions of Section 1.4(b) if the managing underwriter determines in good faith that marketing factors require a limitation of the number of shares to be underwritten.

Section 1.5 Piggy-Back Registration. The Company covenants and agrees that, following the date of this Agreement, it will not grant any Person any Piggy-Back Rights.

Section 1.6 Obligations of the Company. Whenever required under Section 1.4 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities sought to be included therein; provided that, to the extent practicable, at least five (5) Business Days prior to filing any registration statement or prospectus or any amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such registration statement and their counsel copies of all such documents proposed to be filed and any such Holder shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder with respect to such information prior to filing any such registration statement or amendment;

(b) prepare and file with the SEC such amendments and post-effective amendments to any registration statement and any prospectus used in connection therewith as may be necessary to keep such registration statement effective, and cause the prospectus to be supplemented by any required prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act, and to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement for a period of not less than one-hundred twenty (120) days or, if occurring earlier, the date on which the sale of all of the Registrable Securities included in such registration statement shall be completed;

(c) furnish to the Holders such numbers of copies of such registration statement, each amendment and supplement thereto, the prospectus included in such registration statement (including each preliminary prospectus), in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

(d) notify the Holders, promptly after the Company shall receive notice thereof, of the time when a registration statement becomes effective or when any amendment or supplement or any prospectus forming a part of the registration statement has been filed;

(e) notify the Holders promptly of any request by the SEC for the amending or supplementing of any registration statement or prospectus or for additional information and promptly deliver to a Holder copies of any comments received from the SEC to the extent such comments pertain to such Holder;

(f) notify the Holders promptly of any stop order suspending the effectiveness of any registration statement or prospectus or the initiation of any proceedings for that purpose, and use its best efforts to obtain the withdrawal of any such order or the termination of such proceedings;

(g) use its best efforts to register and qualify the securities covered by such registration statement under such other securities or "blue sky" laws of such jurisdictions as shall be reasonably requested by the Holders and use its best efforts to keep each such registration or qualification effective, including through new filings, or amendments or renewals, during the period such registration statement is required to be kept effective; and do any and all other acts or things necessary or advisable to enable the disposition of the Registrable Securities in all such jurisdictions reasonably requested to be covered by such registration, provided that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(h) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of such offering;

(i) use its reasonable efforts to obtain: (A) at the time of effectiveness of each registration statement, a "cold comfort letter" from the Company's independent certified public accountants covering such matters of the type customarily covered by "cold comfort letters" as the Holders of Registrable Securities covered by such registration statement and the underwriters reasonably request; and (B) at the time of any underwritten sale pursuant to the registration statement, a "bring-down comfort letter," dated as of the date of such sale, from the Company's independent certified public accountants covering such matters of the type customarily covered by "bring-down comfort letters" as the Holders of Registrable Securities covered by such registration statement and the underwriters reasonably request;

(j) promptly notify each Holder of Registrable Securities covered by such registration statement at any time when a prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such registration statement or any offering memorandum or other offering document includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing, and prepare a supplement or amendment to such prospectus so that, as thereafter delivered to the purchasers of such shares, such prospectus will not contain an untrue statement or material fact or omit to state any fact necessary to make the statements therein not misleading;

(k) permit any Holder, which Holder in its judgment might be deemed to be an underwriter or a controlling Person of the Company, to participate in the preparation of such registration statement and to require the insertion therein of material, furnished to the Company in writing, which in the reasonable judgment of such Holder and its counsel should be included; and

(1) use its reasonable efforts to obtain an opinion or opinions addressed to the underwriter or underwriters of any underwritten offering of Registrable Securities, if any, in customary form and scope from counsel for the Company; and

 $(m) \qquad \text{use its best efforts to cause all such Registrable} \\ \text{Securities to be listed on each exchange on which similar securities issued by the Company are then listed.}$ 

Section 1.7 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Agreement with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as shall be reasonably necessary to effect the registration of such Holder's Registrable Securities.

Section 1.8 Expenses. Except as specifically provided herein, all Registration Expenses incurred in connection with any registration, qualification or compliance pursuant to Section 1.4 or 1.6 hereof shall be borne by the Company. All Selling Expenses incurred in connection with any registration hereunder shall be borne by the Holders of Registrable Securities covered by a registration statement pro rata on the basis of the number of Registrable Securities registered on their behalf.

Section 1.9 Indemnification. In the event any Registrable Securities are included in a registration statement under this Agreement:

The Company shall indemnify and hold harmless each (a) Holder including Registrable Securities in such registration statement, any underwriter (as defined in the Securities Act) for such Holder and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Securities Exchange Act, against any and all losses, claims, damages, or liabilities (joint or several) to which they may become subject under any securities laws including, without limitation, the Securities Act, the Securities Exchange Act, or any other statute or common law of the United States or any other country or political subdivision thereof, or otherwise, including the amount paid in settlement of any litigation commenced or threatened (including any amounts paid pursuant to or in settlement of claims made under the indemnification or contribution provisions of any underwriting or similar agreement entered into by such Holder in connection with any offering or sale of securities covered by this Agreement), and shall promptly reimburse them, as and when incurred, for any legal or other expenses incurred by them in connection with investigating any claims and defending any actions, insofar as any such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (collectively, a "Violation"): (i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement, including any preliminary prospectus or final prospectus contained therein or amendments or supplements thereto, or in any offering memorandum or other offering document relating to the offering and sale of such securities, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act, the Securities Exchange Act, any state securities law or any rule or regulation promulgated under the Securities Act, the Securities Exchange Act or any state Securities Law; or other applicable laws of any jurisdiction relating to any actual or alleged action or inaction required of the Company in connection with such offering; provided, however, the Company shall not be liable in any such case for any such loss, claim, damage, liability or action to the extent that it arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder.

(b) Each Holder including Registrable Securities in a registration statement shall indemnify and hold harmless the Company, each of its directors, each of its officers who has signed the registration statement, each Person, if any, who controls the Company within the meaning of the Securities Act, any underwriter, any other Holder selling securities in such registration statement and any controlling Person of any such underwriter or other Holder, against any losses, claims, damages, or liabilities (joint or the foregoing Persons may become subject, to which any of liabilities (or actions in respect thereto) which arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation occurs in reliance upon and in conformity with written information furnished by such Holder expressly for use in connection with such registration; and each such Holder shall pay, as incurred, any legal or other expenses reasonably incurred by any Person intended to be indemnified pursuant to this Section 1.9(b), in connection with investigating or defending any such loss, claim, damage, liablity, or action; provided, however, that the indemnity agreement contained in this Section 1.9(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Holder, which consent shall not be unreasonably withheld; provided, that, in no event shall any indemnity under this Section 1.9(b) exceed the net proceeds from the offering received by such Holder.

(c) Promptly after receipt by an indemnified party under this Section 1.9 of notice of the commencement of any action (including any governmental action), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 1.9, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly within any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party shall have the right to retain its own counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 1.9, but the omission so to deliver written notice to the indemnifying party shall not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 1.9.

(d) In order to provide for just and equitable contribution to joint liability in any case in which a claim for indemnification is made pursuant to this Section 1.9 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration or time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 1.9 provided for indemnification in such case, the Company and each Holder of Registrable Securities shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in proportion to the relative fault of the Company, on the one hand, and such Holder, severally, on the other hand; provided, however,

that in any such case, no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation and; provided, further, that in no event shall any contribution under this Section 1.9(d) on the part of any Holder exceed the net proceeds received by such Holder from the sale of Registrable Securities.

(e) The obligations of the Company and the Holders under this Section 1.9 shall survive the completion of any offering of Registrable Securities in a registration statement under this Agreement and otherwise.

Section 1.10 Reports Under Securities Exchange Act. With a view to making available to the Holders the benefits of Rule 144 promulgated under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company agrees to:

 (a) file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Securities Exchange Act; and

(b) furnish to any Holder, so long as such Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144, the Securities Act and the Securities Exchange Act, or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after it so qualifies), (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC (exclusive of Rule 144A) which permits the selling of any such securities without registration or pursuant to such form.

Section 1.11 Assignment of Registration Rights. The rights to cause the Company to register any Registrable Securities pursuant to this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee or assignee of such Registrable Securities that (i) is a subsidiary of a Holder, or (ii) acquires not less than all of the shares of Registrable Securities initially acquired by the Investor on the date of this Agreement (as adjusted for stock splits, stock dividends, stock combinations and the like); provided, however, (A) the transferor shall, within ten (10) days after such transfer, furnish to the Company with written notice of the name and address of such transferee or assignee and, in the case of a transfer in accordance with subclause (i) above, details of the Registrable Securities with respect to which such registration rights are being assigned, (B) such transferee or assignee, prior to such transfer or assignment, shall agree in writing to be subject to and bound by all restrictions set forth in this Agreement including the provisions of Article II, and (C) such transfer or assignment shall be effective only if immediately following such transfer or assignment the further disposition of such Registrable Securities by the transferee or assignee is restricted under the Securities Act and other applicable securities law.

Section 1.12 Rule 144. The Company shall not be required to include the Registrable Securities of any Holder in a registration statement filed pursuant to Section 1.4 if the Company delivers to such Holder(s) an opinion of counsel, in form and substance reasonably acceptable to such Holder(s), to the effect that the Registrable Securities requested to be included in such Registration by the Holder may then be sold pursuant to Rule 144(k) of the Securities Act.

# ARTICLE II.

# RESTRICTIONS ON ACQUISITIONS AND DISPOSITIONS

Section 2.1 Standstill. Prior to the earlier of (i) the termination by the Investor of the Collaboration Agreement pursuant to Section 19.5 thereof, and (ii) the fifth anniversary of the date of this Agreement, without the express written consent of the Company, the Investor and its Affiliates shall not:

(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, the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act) more than nineteen and nine-tenths percent (19.9%) of the Shares of Then Outstanding Capital Stock; provided, however, that notwithstanding the provisions of this Section 2.1(a), 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 the Company, the 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 the Investor's ownership exceeding nineteen and nine-tenths percent (19.9%) of the Shares of Then Outstanding Capital Stock;

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

(c) directly or indirectly, encourage 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 the Company (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 the Company 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 the Company or any of its subsidiaries;

(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; or

(f) instigate, act in concert with or assist any third party to take any action in clauses (a) through (e) above;

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

Section 2.2 Termination of Standstill. The restrictions contained in Section 2.1 shall terminate upon the earlier to occur of (i) the public announcement by an Offeror of an Acquisition Proposal; (ii) the acquisition by an Offeror (other than Leonard Schleifer) 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 twenty percent (20%) of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock; (iii) the entry by the Company into negotiations with any third party or group with respect to a transaction which, if consummated, would result in a "change of control," (iv) the issuance by the Company to a third party of Shares of Then Outstanding Capital Stock which, when combined with all other Shares of Then Outstanding Shares of Then Outstanding Capital Stock beneficially owned by such third party, represents more than seven percent (7%) of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock, if the Company does not enter into a standstill agreement for a time period and upon terms substantially similar to the provisions of this Section 2; (v) a sale of all or substantially all of the assets of the Company (other than to a wholly owned subsidiary of the Company); or (vi) a liquidation or dissolution of the Company.

Section 2.3 Change of Control. For purposes this Article II, a "change of control" shall mean (i) a merger or consolidation to which the Company is a party and as a result of which the Persons who were stockholders of the Company immediately prior to the effective date of such merger or consolidation beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act) less than fifty percent (50%) of the voting stock of the surviving parent entity outstanding immediately following the effectiveness of such merger or consolidation; (ii) a sale of all or substantially all of the Company's assets (other than to a wholly-owned subsidiary of the Company); or (iii) a liquidation or dissolution of the Company.

Section 2.4 Lock-Up. Prior to the second anniversary of the date of this Agreement (the "Lock-up Period"), without the approval of a majority of the Board of Directors of the Company, the Investor shall not sell or otherwise transfer, directly or indirectly, Registrable Securities (each, a "Transfer"), provided, however that the foregoing shall not prohibit the Investor from transferring all or part of the Purchased Stock to a subsidiary which agrees to be bound by the terms hereof, and provided, further, that, subject to compliance with the terms of Section 2.5, during the Lock-up Period the Company may Transfer Registrable Securities in a transaction that is exempt from the registration requirements of the Securities Act (other than pursuant to Rule 144 under the Securities Act) (a "Permitted Transfer") subject to the terms of Section 2.5.

#### Section 2.5 Permitted Transfer; Right of First Offer.

(a) Prior to a Permitted Transfer to any Person of Registrable Securities by the Investor, the Investor shall give written notice (the "Sale Notice") to the Company. The Sale Notice shall (i) disclose the price and terms upon which the Investor is willing to sell to the Company some or all of the Registrable Securities held by it (the "Offered Registrable Securities"), and (ii) confirm that the offer to purchase such Registrable Securities is irrevocable for a period of at least ten (10) days (the "Notice Period"). The Investor shall not consummate any Transfer until the earlier of (x) the conclusion of the Notice Period and (y) the date on which the Company notifies the Investor that it does not wish to purchase all (but not less than all) of the Offered Registrable Securities (such earlier date, the "Authorization Date").

(b) The Company may elect to purchase all (but not less than all) of the Offered Registrable Securities upon the same terms and conditions as those set forth in the Sale Notice by delivering a written notice of such election to the Investor within ten (10) days after the Sale Notice has been delivered to the Company. If the Company has not elected to purchase all of the Offered Registrable Securities within ten (10) days after the Sale Notice has been delivered to Company, the Investor may, during the sixty (60) day period immediately following the Authorization Date, Transfer all such Offered Registrable Securities specified in the Sale Notice. Any Offered Registrable Securities not Transferred during such sixty (60) day period shall be subject to the provisions of this Section 2.5 upon a subsequent proposed Transfer prior to the end of the Lock-up Period.

(c) If the Company has agreed to purchase all of the Offered Registrable Securities set forth in the Sale Notice pursuant to Section 2.5(b), the closing of such purchase shall occur within ten (10) Business Days from the date the Company has notified the Investor of its intention to purchase all of such Offered Registrable Securities.

Section 2.6 Legend.

(a) Prior to the termination of the Lock-Up Period, each certificate representing Registrable Securities shall bear the following legend:

PURSUANT TO THE TERMS AND CONDITIONS OF A REGISTRATION RIGHTS AGREEMENT DATED MARCH 27, 2003, BY AND BETWEEN THE COMPANY AND NOVARTIS PHARMA A.G., THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD OR OTHERWISE TRANSFERRED PRIOR TO MARCH 28, 2005.

(b) Following the termination of the Lock-Up Period, the holder of any stock certificate bearing such legend may submit such certificate to the Company in exchange for a share certificate duly issued by the Company which shall be identical in all material respects, except that it shall not bear the foregoing legend.

Section 2.7 Injunctive Relief. It is hereby agreed and acknowledged that it will be impossible to measure in money the damages that would be suffered by the Company if the Investor fails to comply with the terms of this Article II and that in the event of any such failure, the Company will be irreparably damaged and will not have an adequate remedy at law. Each party agrees (i) that in any action for equitable remedies arising from a breach of this Article II, the Company will not be required to prove the inadequacy or insufficiency of money damages as a remedy and (ii) to waive any requirement for a bond in connection with any such injunctive or equitable relief or action therefor.

### ARTICLE III.

#### MISCELLANEOUS

Section 3.1 Amendment; Waiver. Any term of this Agreement may be amended or waived only with the written consent of the Company and the Holders of at least two-thirds (2/3) of the Registrable Securities then outstanding; provided, however, that Section 2 may be amended or waived solely with the written consent of the Company and the Investor.

Section 3.2 Remedies. In case any one or more of the covenants or agreements set forth in this Agreement shall have been breached by any party hereto, the party or parties entitled to the benefit of such covenants or agreements may proceed to protect and enforce their rights either by suit in equity or action at law, including, but not limited to, an action for damages as a result of any such breach or an action for specific performance of any such covenant or agreement contained in this Agreement. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

Section 3.3 Successors and Assigns. Except as otherwise expressly provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. This Agreement and the rights and duties of the Company set forth herein may not be assigned, in whole or in part, by the Company.

Section 3.4 Entire Agreement. This Agreement, together with the Stock Purchase Agreement (including exhibits thereto), contains the complete understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating to the subject matter hereof.

Section 3.5 Governing Law; Consent 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. Each of the parties irrevocably submits to the exclusive jurisdiction of (a) the Supreme Court of the State of New York, and (b) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each of the parties agrees to commence any action, suit or proceeding relating hereto in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional purposes, in the Supreme Court of the State of New York.

Section 3.6 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.

Section 3.7 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

Section 3.8 Nouns and Pronouns. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa.

Section 3.9 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the Holder set forth below or as provided to the Company upon any Person becoming a Holder, 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 on a Business Day; or otherwise, on the next Business Day following such transmission). Any Holder may change its address by giving notice to the Company and the Company may change its address by giving notice to the Holders in the manner provided above.

To the Company:	Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill Road Tarrytown, New York 10591 Attention: General Counsel
With a copy (which shall not constitute notice) to:	Skadden, Arps, Slate, Meagher & Flom LLP 4 Time Square New York, NY 10036 Attention: David J. Goldschmidt, Esq.
To the Investor:	Novartis Pharma AG Lichtstrasse 35 CH-4002 Basel Switzerland Attention: General Counsel
With a copy to (which: shall not constitute notice) to	

Section 3.10 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 ("Severed Clause"), then, it is mutually agreed that this Agreement shall endure except for the Severed Clause. The parties shall consult and use their best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

NOVARTIS PHARMA AG

By: /s/ Joseph E. Mamie Name: Joseph E. Mamie Title: Head Operational Treasury

By: /s/ Kim Urdahl -----Name: Kim Urdahl Title: Head of Legal, Primary Care

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski -----Name: Stuart Kolinski Title: Vice President & General Counsel

SCHEDULE 1.4(C)

Class D Convertible Preferred Stock Purchase Agreement dated as of August 31, 1990, between the Company and Amgen, Inc.

## Exhibit 99.1

#### 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 ending March 31, 2003 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. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Leonard S. Schleifer Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer May 15, 2003

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer May 15, 2003

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.