REGENERON PHARMACEUTICALS INC
Form 10-Q
May 15, 2003

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 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	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes 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	2,408,548
Common Stock, $0.001 par value	44,497,128

TABLE OF CONTENTS

Table of Contents

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

Table of Contents

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.

Table of Contents

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

	Three months ended March 31, 2003	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.

Table of Contents

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

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation
	Shares	Amount	Shares	Amount		
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.

Table of Contents

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

Table of Contents

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

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company s financial position, results of operations, and cash flows in conformity with 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.*

Table of Contents

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 ended 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.

Table of Contents

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

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

[1] Net of reserves of $1,921.

[2] Net of reserves of $32.

[3] Net of reserves of $1,223.

Table of Contents

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

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.

Table of Contents

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

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.

Table of Contents

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

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 Ended March 31, 2003	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

Table of Contents

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.

Table of Contents

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

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.

Table of Contents

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. AXOKINE-associated 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

Table of Contents

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. AXOKINE-associated 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,

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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 non-refundable 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 three years after the initial product launch of the IL-1 Trap or three years after termination of 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

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

SIGNATURE

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

Regeneron Pharmaceuticals, Inc.

Date: May 15, 2003

By: /s/ Murray A. Goldberg

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

Table of Contents

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

Table of Contents

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

Table of Contents

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