

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2002

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 No

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of April 30, 2002:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$0.001 par value	2,500,786
Common Stock, \$0.001 par value	41,507,069

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT MARCH 31, 2002 AND DECEMBER 31, 2001 (Unaudited)

(In thousands, except share data)

ASSETS	March 31, 2002	December 31, 2001
Current assets		
Cash and cash equivalents	\$ 135,469	\$ 247,393
Marketable securities	178,659	126,796
Restricted marketable securities	10,942	10,890
Receivable due from The Procter & Gamble Company	2,593	2,665
Receivable due from Merck & Co., Inc.	67	63
Receivable due from Amgen-Regeneron Partners	79	247
Prepaid expenses and other current assets	4,320	2,159
Inventory	4,989	3,973
Total current assets	337,118	394,186
Marketable securities	63,352	32,420
Restricted marketable securities	21,015	20,884
Investment in Amgen-Regeneron Partners	919	921
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	42,043	39,448
Other assets	7,418	7,538
Total assets	\$ 471,865	\$ 495,397
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 17,068	\$ 14,830
Deferred revenue, current portion	5,464	6,766
Capital lease obligations, current portion	412	426
Total current liabilities	22,944	22,022
Deferred revenue	6,384	6,870
Capital lease obligations	53	150
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; 2,516,186 shares issued and outstanding in 2002		
2,562,689 shares issued and outstanding in 2001	3	3
Common Stock, \$.001 par value; 160,000,000 shares authorized; 41,474,330 shares issued and outstanding in 2002		
41,264,280 shares issued and outstanding in 2001	41	41
Additional paid-in capital	569,613	567,624
Unearned compensation	(2,407)	(2,789)
Accumulated deficit	(325,143)	(299,698)
Accumulated other comprehensive income	377	1,174
Total stockholders' equity	242,484	266,355
Total liabilities and stockholders' equity	\$ 471,865	\$ 495,397

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 March 31,	
	2002	2001
Revenues		
Contract research and development	\$ 2,690	\$ 3,414
Contract manufacturing	2,251	2,899
	<u>4,941</u>	<u>6,313</u>
Expenses		
Research and development	25,475	16,805
Contract manufacturing	1,259	2,188
General and administrative	3,400	2,031
	<u>30,134</u>	<u>21,024</u>
Loss from operations	<u>(25,193)</u>	<u>(14,711)</u>
Other income (expense)		
Investment income	2,772	2,772
Loss in Amgen-Regeneron Partners	(2)	(1,051)
Interest expense	(3,022)	(47)
	<u>(252)</u>	<u>1,674</u>
Net loss	<u>(\$25,445)</u>	<u>(\$13,037)</u>
Net loss per share amounts, basic and diluted	<u>(\$0.58)</u>	<u>(\$0.35)</u>

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, 2002

(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation
	Shares	Amount	Shares	Amount		
Balance, December 31, 2001	2,563	\$3	41,264	\$41	\$567,624	(\$2,789)
Issuance of Common Stock in connection with exercise of stock options			139		1,168	
Issuance of restricted Common Stock under Long-Term Incentive Plan			2		57	(57)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			22		764	
Conversion of Class A Stock to Common Stock	(47)		47			
Amortization of unearned compensation						439
Net loss						
Change in net unrealized gain on marketable securities						
Balance, March 31, 2002	2,516	\$3	41,474	\$41	\$569,613	(\$2,407)

[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, 2001	(\$299,698)	\$1,174	\$266,355	
Issuance of Common Stock in connection with exercise of stock options			1,168	
Issuance of restricted Common Stock under Long-Term Incentive Plan				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			764	
Conversion of Class A Stock to Common Stock				
Amortization of unearned compensation			439	
Net loss	(25,445)		(25,445)	(\$25,445)
Change in net unrealized gain on marketable securities		(797)	(797)	(797)
Balance, March 31, 2002	(\$325,143)	\$ 377	\$242,484	(\$26,242)

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

REGENERON PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

(In thousands)

	Three months ended March 31,	
	2002	2001
Cash flows from operating activities		
Net loss	(\$25,445)	(\$13,037)
Adjustments to reconcile net loss to net cash used in operating activities		
Loss in Amgen-Regeneron Partners	2	1,051
Depreciation and amortization	2,008	1,329
Non-cash compensation expense	439	181
Changes in assets and liabilities		
Decrease in amounts due from The Procter & Gamble Company	72	4,407
(Increase) decrease in amounts due from Merck & Co., Inc.	(4)	1,240
Decrease (increase) in amounts due from Amgen-Regeneron Partners	168	(290)
Increase in amounts due from Sumitomo Pharmaceuticals Company, Ltd.		(130)
Increase in investment in Amgen-Regeneron Partners		(552)
Increase in prepaid expenses and other assets	(3,150)	(609)
Increase in inventory	(735)	(474)
Decrease in deferred revenue	(1,788)	(1,328)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	2,379	(185)
Total adjustments	(609)	4,640
Net cash used in operating activities	(26,054)	(8,397)
Cash flows from investing activities		
Purchases of marketable securities	(127,745)	(15,378)
Sales of marketable securities	44,818	23,908
Capital expenditures	(4,000)	(1,643)
Net cash (used in) provided by investing activities	(86,927)	6,887
Cash flows from financing activities		
Net proceeds from the issuance of stock	1,168	154,382
Principal payments on note payable		(16)
Capital lease payments	(111)	(214)
Net cash provided by financing activities	1,057	154,152
Net (decrease) increase in cash and cash equivalents	(111,924)	152,642
Cash and cash equivalents at beginning of period	247,393	30,978
Cash and cash equivalents at end of period	\$ 135,469	\$ 183,620

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

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(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, 2001 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, 2001.

2. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

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 March 31, 2001 are \$869 of accrued capital expenditures and \$421 of costs incurred in connection with the Company's sale of Common Stock in a public offering. Included in accounts payable and accrued expenses at December 31, 2000 are \$672 of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2001 and 2000 are \$764 and \$477, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2002 and 2001, the Company contributed 21,953 and 17,484 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2002 and December 31, 2001 are \$2,652 and \$1,988, respectively, of accrued interest income. Included in restricted marketable securities at March 31, 2002 and December 31, 2001 are \$183 and \$154, respectively, of accrued interest income. Included in marketable securities at March 31, 2001 and December 31, 2000 are \$2,573 and \$2,541, respectively, of accrued interest income.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Dollars in thousands, except per share data)

3. Inventories

Inventories consist primarily 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, 2002 and December 31, 2001 consist of the following:

	March 31, 2002	December 31, 2001
Raw materials	\$ 401	\$ 374
Work-in-process	738	227(1)
Finished products	3,850	3,372
	<u>\$4,989</u>	<u>\$3,973</u>

(1) Net of reserves of \$230.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2002 and December 31, 2001 consist of the following:

	March 31, 2002	December 31, 2001
Accounts payable	\$ 3,221	\$ 3,007
Accrued payroll and related costs	3,239	3,662
Accrued clinical trial expense	906	2,583
Accrued expenses, other	4,661	3,286
Interest payable on convertible notes	5,041	2,292
	<u>\$17,068</u>	<u>\$14,830</u>

5. Amgen-Regeneron Partners Research Collaboration Agreement

In August 1990, the Company entered into a collaboration with Amgen Inc. ("Amgen") to develop and attempt to commercialize brain derived neurotrophic factor ("BDNF") and neurotrophin-3 ("NT-3") in the United States. Pursuant to that agreement, the Company and Amgen formed a partnership, Amgen-Regeneron Partners (the "Partnership"). The Company accounts for its investment in the Partnership in accordance with the equity method of accounting. The partnership has no ongoing development activities for BDNF or NT-3 at this time.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Dollars in thousands, except per share data)

Selected operating statement data of the Partnership for the three months ended March 31, 2002 and 2001 is as follows:

	Three Months Ended March 31,	
	2002	2001
Interest income	\$ 11	\$ 69
Total expenses	(15)	(2,170)
Net income (loss)	(\$4)	(\$2,101)

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, 2002 and 2001, the components of comprehensive loss are:

	Three Months Ended March 31,	
	2002	2001
Net loss	(\$25,445)	(\$13,037)
Change in net unrealized gain on marketable securities	(797)	699
Total comprehensive loss	(\$26,242)	(\$12,338)

7. Stock Compensation

The Company awards shares of Restricted Stock under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Restrictions on these shares lapse with respect to 25% of the shares every six months over 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 two year period that the restrictions lapse. For the three months ended March 31, 2002 and 2001, the Company recognized compensation expense related to Restricted Stock awards of \$439 and \$181, respectively.

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, 2002 and 2001, 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:

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Dollars in thousands, except per share data)

	Three Months Ended March 31,		
	Net Loss, in thousands (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2002:			
Basic and Diluted	(\$25,445)	43,822	(\$0.58)
2001:			
Basic and Diluted	(\$13,037)	37,434	(\$0.35)

Options, warrants, and 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,	
	2002	2001
Options and Warrants:		
Weighted Average Number, in thousands	9,423	7,621
Weighted Average Exercise Price	\$21.46	\$18.93
Convertible Debt:		
Weighted Average Number, in thousands	6,611	
Conversion Price	\$30.25	

9. Segment Reporting

The Company's operations are principally 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 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.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Dollars in thousands, except per share data)

The tables below present information about reported segments for the three months ended March 31, 2002 and 2001:

	Three Months Ended March 31, 2002			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 2,690	\$ 2,251	—	\$ 4,941
Loss in Amgen-Regeneron				
Partners	(2)	—	—	(2)
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

	Three Months Ended March 31, 2001			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 3,414	\$ 2,899	—	\$ 6,313
Loss in Amgen-Regeneron				
Partners	(1,051)	—	—	(1,051)
Depreciation and amortization	1,329	— ⁽¹⁾	—	1,329
Interest expense	33	14	—	47
Net (loss) income	(16,506)	697	\$ 2,772 ⁽⁴⁾	(13,037)
Capital expenditures	1,839	—	—	1,839
Total assets	35,523	12,919	300,743 ⁽³⁾	349,185

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory.

(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.

(4) Represents investment income.

10. Legal Matters

The Company, from time to time, has been subject to legal claims arising in connection with its business. While the ultimate results of the legal claims cannot be predicted with certainty, at March 31, 2002 there were no asserted claims against the Company which, in the opinion of management, if adversely decided would have a material adverse effect on the Company's financial position, results of operations, and cash flows.

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., which may be referred to as “we”, “us”, or “our”, is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic drugs for the treatment of serious medical conditions. Our product 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 drugs 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 science and technology with state-of-the-art manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse and growing pipeline of product candidates that have the potential to address a variety of unmet medical needs. Our ability to develop product candidates results from the application of our technology platforms. In contrast to basic genomics approaches which attempt to identify every gene in a cell or genome, our technology platforms are designed to discover specific genes of therapeutic interest for a particular disease or cell type. We will continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

A key aspect of our strategy is to retain significant ownership and commercialization rights to our pipeline. Below is a summary of our leading clinical programs, as well as several product candidates that are expected to enter clinical trials over the next two years. We retain sole ownership and marketing rights for each of these programs and currently are developing them independent 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 November 2000, we announced the preliminary results of a twelve-week Phase II dose-ranging trial of AXOKINE in 170 severely obese patients. In the trial, AXOKINE was generally well tolerated and patients treated with AXOKINE showed medically meaningful and statistically significant weight loss compared to those receiving placebo. In September 2001, we reported that patients who completed 36 weeks of follow-up after cessation of AXOKINE treatment, on average, maintained the weight loss observed in the twelve-week treatment period. In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese patients. In January 2002, we announced that we had completed enrollment for a pivotal trial that includes approximately 2,000 patients in 65 sites across the United States. In April 2002, we announced that we had initiated two additional trials to evaluate shorter dosing periods for AXOKINE and study long-term maintenance of weight loss following cessation of treatment.
- **PEGYLATED AXOKINE:** Chemically modified version of AXOKINE that is being developed as a more potent, longer-acting form of the protein. Pegylated AXOKINE currently is in late-stage preclinical development and we anticipate initiating a Phase I clinical trial in mid-2002.
- **INTERLEUKIN-1 CYTOKINE TRAP (IL1 Trap):** Protein-based antagonist for the interleukin-1 (called IL1) cytokine. IL1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In December 2000, we initiated a Phase I study to assess the safety and tolerability of the IL1 Trap in patients with rheumatoid arthritis. In January 2002, we reported positive preliminary results from the trial. Patients treated with the IL1 Trap experienced dose-dependent improvements in tender and swollen joints and CRP (C-Reactive Protein) levels, as well as the composite ACR (American College of Rheumatology) measure of disease activity. We expect to initiate a Phase II study for the IL1 Trap in patients with rheumatoid arthritis in mid-2002.
- **INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL4/IL13 Trap):** Protein-based antagonist for the interleukin-4 and interleukin-13 (called IL4 and IL13) cytokines which are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. We expect to initiate a Phase I clinical trial of a dual IL4/IL13 Trap for asthma/allergy-related conditions in mid-2002.
- **VEGF TRAP:** Protein-based antagonist to Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF). 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 Phase I clinical trial designed to assess the safety and tolerability of VEGF Trap in

patients with solid tumor malignancies and patients with non-Hodgkin's lymphoma.

- **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. Selected Angiopoietins, including engineered forms of these growth factors, are in preclinical development.

In addition to the above programs which we are conducting independent of any corporate partners, 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 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 2002 Activities

In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese patients. We announced in January 2002 that the initial trial was fully enrolled with approximately 2,000 patients at 65 sites across the United States. This trial is a double-blind, randomized, placebo-controlled study. It will have a twelve-month treatment period, in which patients will receive daily subcutaneous self-injections of placebo or AXOKINE at a dose of 1.0 microgram (mcg) per kilogram (kg) of body weight. The treatment period will be followed by a twelve-month open-label safety extension phase, during which all patients will receive AXOKINE. Endpoints of the study are based on changes in body weight versus baseline during the treatment period. In April 2002, we initiated two additional studies in the AXOKINE Phase III program for the treatment of obesity. Each study will involve approximately 300 patients. The randomized, double blind studies will assess the safety and efficacy of AXOKINE compared with placebo in two different dosing periods, and will be conducted at approximately 20 sites within the United States. Participants in the first study will be given AXOKINE or placebo for 6 months and will then be observed for another 6 months off-treatment. The companion study will treat subjects with AXOKINE or placebo for 3 months and observe them for an additional 9 months off-treatment. The trials will run concurrently. At the end of the initial 12-month treatment and observation period for the two studies, participants will again receive AXOKINE or placebo for a brief re-treatment period. In total, each study will run 18 months from enrollment to completion. The primary end-point of these studies is weight loss at the end of 12 months. As part of the overall Phase III program, Regeneron will conduct additional confirmatory and ancillary studies of AXOKINE in obese and obese diabetic patients. These studies will vary in

duration and size and are planned to be completed within a similar time frame as the initial pivotal study described above. The Phase III program is expected to enroll over 4,000 subjects in total.

In December 2000, we initiated a Phase I study of the IL1 Trap to assess its safety and tolerability in patients with rheumatoid arthritis. The placebo-controlled, double-blind, dose-escalation study was conducted at several centers in the United States and included a single dose phase and a multiple dose phase. In January 2002, we reported positive preliminary results from the trial. The preliminary results indicated that patients treated with the IL1 Trap experienced dose dependent improvements in tender and swollen joints and CRP levels as well as the composite ACR measure of disease activity. We expect to initiate a Phase II study of the IL1 trap in patients with rheumatoid arthritis in mid-2002.

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 patients with non-Hodgkin's lymphoma. The Phase I trial is an open-label study in patients 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.

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, IL1 Trap, or VEGF 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, 2002, we had a cumulative loss of \$325.1 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, 2002 and 2001. Our total revenue decreased to \$4.9 million for the first quarter of 2002 from \$6.3 million for the same period in 2001. Contract research and development revenue decreased to \$2.7 million for the first quarter of 2002 from \$3.4 million for the same period in 2001 due to the substantial completion of studies conducted on behalf of Amgen-Regeneron Partners. 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 \$2.3 million in the first quarter of 2002 from \$2.9 million for the same period in 2001, because we shipped less product to Merck. Contract manufacturing revenue and the related manufacturing expense are recognized as product is accepted and shipped. Product that we manufactured for Merck in the end of 2001 and the first quarter of 2002 will not be shipped until later this year.

Our total operating expenses increased to \$30.1 million in the first quarter of 2002 from \$21.0 million for the same period in 2001. Research and development expenses increased to \$25.5 million in the first quarter of 2002 from \$16.8 million for the comparable period in 2001. In the first quarter of 2002, activity in our clinical research programs increased, especially related to our Phase III clinical program for AXOKINE, which we initiated in July 2001. The first quarter 2002 increase in research and development expenses also resulted, in part, from higher staffing as we continued to expand our research programs and the technology platforms supporting that research. Research and development expenses were 85% of total operating expenses in the first quarter of 2002, compared to 80% for the same period in 2001. Contract manufacturing expenses related to our long-term agreement with Merck decreased to \$1.3 million in the first quarter of 2002 from \$2.2 million for the same period in 2001, primarily due to the above-described decrease in shipments of product to Merck and higher manufacturing costs in the first quarter of 2001. General and administrative expenses increased to \$3.4 million in the first quarter of 2002 from \$2.0 million for the same period of 2001, due primarily to higher patent-related expenditures to protect our intellectual property portfolio and higher administrative staffing to support the growth of the company.

Investment income was \$2.8 million for both the first quarter of 2002 and 2001. The loss in Amgen-Regeneron Partners decreased to approximately \$2,000 in the first quarter of 2002 compared to \$1.1 million for the same period in 2001 due to the substantial completion of Phase II studies of NT-3. Interest expense increased by \$3.0 million in the first three months of 2002 compared to the same period in 2001 due to interest incurred on the \$200.0 million aggregate principal amount of convertible senior subordinated notes issued in October 2001. These notes bear interest at 5.5% per annum, payable semi-annually.

Our net loss for the first quarter of 2002 was \$25.4 million, or \$0.58 per share (basic and diluted), compared to a net loss of \$13.0 million, or \$0.35 per share (basic and diluted), for the same period in 2001.

Liquidity and Capital Resources

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

We and Procter & Gamble have a long-term collaboration agreement. Under our agreement, since the first quarter of 2001 and through December 2005, Procter & Gamble provides funding in support of our research efforts related to the collaboration of \$2.5 million per quarter, plus adjustments for inflation.

We are compensated by Amgen-Regeneron Partners for services we render on behalf of the partnership, and we recognize these amounts as revenue. We and Amgen fund Amgen-Regeneron Partners through capital contributions. We expect to continue funding 50% of the development costs of the partnership in order to maintain equal ownership and equal sharing of the profits or losses of the partnership. Our aggregate capital contribution to Amgen-Regeneron Partners from the partnership's inception in June 1993 through March 31, 2002 was \$57.9 million. We do not expect to make capital contributions to the partnership in 2002 since there are currently no ongoing development activities. Additional contributions may be required, if, among other things, Amgen-Regeneron Partners initiates any new development activities.

At March 31, 2002, we had \$409.4 million in cash, cash equivalents, marketable securities, and restricted marketable securities. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of March 31, 2002, 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 \$4.6 million and \$1.8 million for the first three months of 2002 and 2001, respectively. During March 2002, we entered into a new sublease for additional space at our Tarrytown location, which expires in December 2005. The base rent under the new sublease will be \$0.3 million per year, excluding costs for utilities, real estate taxes, and operating expenses.

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 anticipate that expenses for research and development will increase in 2002 by more than 30% over 2001 amounts. We currently anticipate that for the remainder of 2002, approximately 50-70% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including AXOKINE, pegylated AXOKINE, IL1 Trap, IL4/13 Trap, VEGF Trap, and the angiopoietins; approximately 5-15% will be invested in expansion of our manufacturing facilities; approximately 10-30% will cover our basic research activities; approximately 5-15% 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 administrative expenses and working capital. During the remainder of 2002, we expect to lease additional space in both our Tarrytown and Rensselaer locations and incur approximately \$50 million in capital expenditures for our expanded manufacturing and research and development activities.

We anticipate 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 potential drug candidates, and the continuation, extent, and success of any collaborative research arrangements (including those with Procter & Gamble, 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, and 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 2003. 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.

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 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, the agreement with Procter & Gamble) and the resulting loss of research or other funding could have a material adverse effect on us and our operations. A change of control of one or more of our material collaborators or licensees could also have a material adverse effect on us.
- Delay, difficulty, or failure of a clinical trial of any of our product candidates. 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 patients, 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.
- 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. Patients who have received AXOKINE in clinical trials have developed antibodies.

- Delay, difficulty, or failure in obtaining regulatory approval (including approval of our facilities for production) for our products, including delays or difficulties in development because of insufficient proof of safety or efficacy.
- 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 intellectual property rights, either by license, collaboration, or purchase of another entity.
- Difficulties or high costs of obtaining adequate financing to fund the cost of developing 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 product in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.
- 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, such as product- or employment-related, or environmental, or criminal), 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.

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.

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.

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits
None

(b) Reports
None

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 10, 2002

By: -s- Murray A. Goldberg

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