

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, 2000

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, 2000:

Class of Common Stock	Number of Shares
-----	-----
Class A Stock, \$0.001 par value	2,771,745
Common Stock, \$0.001 par value	32,284,125

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT MARCH 31, 2000 AND DECEMBER 31, 1999 (Unaudited)
(In thousands, except share data)

ASSETS	March 31, 2000	December 31, 1999
	-----	-----
Current assets		
Cash and cash equivalents	\$12,294	\$23,697
Marketable securities	44,120	42,463
Receivable due from The Procter & Gamble Company	7,046	
Receivable due from Merck & Co., Inc.	49	
Receivable due from Amgen-Regeneron Partners	1,256	473
Receivable due from Sumitomo Pharmaceuticals Company, Ltd.	209	151
Prepaid expenses and other current assets	2,866	1,708
Inventory	5,641	4,552
	-----	-----
Total current assets	73,481	73,044
Marketable securities	21,479	27,439
Investment in Amgen-Regeneron Partners	56	
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	36,630	36,298
Other assets	388	218
	-----	-----
Total assets	\$132,034	\$136,999
	=====	=====
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$6,921	\$6,551
Deferred revenue, current portion	4,177	4,686
Due to Merck & Co., Inc.		334
Due to Amgen-Regeneron Partners		300
Capital lease obligations, current portion	1,284	1,380
Note payable, current portion	68	68
	-----	-----
Total current liabilities	12,450	13,319
Deferred revenue	11,179	11,130
Capital lease obligations	1,007	1,204
Note payable	1,513	1,527
Other liabilities	290	287
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; 2,773,950 shares issued and outstanding in 2000		
3,605,133 shares issued and outstanding in 1999	3	4
Common Stock, \$.001 par value; 60,000,000 shares authorized; 29,676,406 shares issued and outstanding in 2000		
27,817,636 shares issued and outstanding in 1999	30	28
Additional paid-in capital	313,699	310,296
Accumulated deficit	(207,621)	(200,303)
Accumulated other comprehensive loss	(516)	(493)
	-----	-----
Total stockholders' equity	105,595	109,532
	-----	-----
Total liabilities and stockholders' equity	\$132,034	\$136,999
	=====	=====

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,	
	2000	1999
	-----	-----
Revenues		
Contract research and development	\$9,122	\$3,344
Contract manufacturing	1,376	2,115
Investment income	1,226	1,459
	-----	-----
	11,724	6,918
	-----	-----
Expenses		
Research and development	11,975	11,221
Loss in Amgen-Regeneron Partners	1,271	966
General and administrative	1,755	1,593
Depreciation and amortization	926	725
Contract manufacturing	3,051	1,254
Interest	64	89
	-----	-----
	19,042	15,848
	-----	-----
Net loss	(\$7,318)	(\$8,930)
	=====	=====
Net loss per share, basic and diluted	(\$0.23)	(\$0.29)
	=====	=====

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, 2000
 (In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	
Balance, December 31, 1999	3,605	\$4	27,818	\$28	\$310,296
Issuance of Common Stock in connection with exercise of stock options			495	1	2,982
Net issuance of Common Stock to Amgen in connection with a cashless exercise of warrants			478		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			54		421
Conversion of Class A to Common Stock	(831)	(1)	831	1	
Net loss					
Change in net unrealized loss on marketable securities					
Balance, March 31, 2000	2,774	\$3	29,676	\$30	\$313,699

	Accumulated	Accumulated	Total	Comprehensive
	Deficit	Other Comprehensive Loss	Stockholders' Equity	Loss
Balance, December 31, 1999	(\$200,303)	(\$493)	\$109,532	
Issuance of Common Stock in connection with exercise of stock options			2,983	
Net issuance of Common Stock to Amgen in connection with a cashless exercise of warrants				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			421	
Conversion of Class A to Common Stock				
Net loss	(7,318)		(7,318)	(\$7,318)
Change in net unrealized loss on marketable securities		(23)	(23)	(23)
Balance, March 31, 2000	(\$207,621)	(\$516)	\$105,595	(\$7,341)

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
Increase (Decrease) in Cash and Cash Equivalents
(In thousands)

	Three months ended March 31, 2000	1999
	-----	-----
Cash flows from operating activities		
Net loss	(\$7,318)	(\$8,930)
	-----	-----
Adjustments to reconcile net loss to net cash used in operating activities		
Loss in Amgen-Regeneron Partners	1,271	966
Depreciation and amortization	926	725
Stock issued in consideration for services rendered		90
Changes in assets and liabilities		
Increase in amounts due from The Procter & Gamble Company	(7,046)	(386)
Increase in amounts due from Merck & Co., Inc.	(383)	(903)
(Increase) decrease in amounts due from Amgen-Regeneron Partners	(783)	119
Increase in amounts due from Sumitomo Pharmaceuticals Co., Ltd.	(58)	(15)
Increase in investment in Amgen-Regeneron Partners	(1,627)	
(Increase) decrease in prepaid expenses and other assets	(1,328)	66
Increase in inventory	(700)	
Decrease in deferred revenue	(460)	(1)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	919	(158)
	-----	-----
Total adjustments	(9,269)	503
	-----	-----
Net cash used in operating activities	(16,587)	(8,427)
	-----	-----
Cash flows from investing activities		
Purchases of marketable securities	(5,984)	(22,857)
Sales of marketable securities	10,264	33,685
Capital expenditures	(1,771)	(993)
	-----	-----
Net cash provided by investing activities	2,509	9,835
	-----	-----
Cash flows from financing activities		
Net proceeds from the issuance of stock	2,983	892
Principal payments on note payable	(14)	(16)
Capital lease payments	(294)	(264)
	-----	-----
Net cash provided by financing activities	2,675	612
	-----	-----
Net (decrease) increase in cash and cash equivalents	(11,403)	2,020
	-----	-----
Cash and cash equivalents at beginning of period	23,697	19,757
	-----	-----
Cash and cash equivalents at end of period	\$12,294	\$21,777
	=====	=====

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

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. (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, 1999 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, 1999.

2. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2000 and December 31, 1999 were \$572 and \$697, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 1999 and December 31, 1998 were \$1,421 and \$469, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 1999 and 1998 were \$421 and \$308, respectively, of accrued Company 401(k) Savings Plan contribution expense. During January 2000 and 1999, the Company contributed 54,003 and 37,653 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

3. Inventories

Inventories consist of raw materials and other direct and indirect costs associated with the production of brain-derived neurotrophic factor ("BDNF") for Sumitomo Pharmaceuticals Company, Ltd. under a research and development agreement and the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement.

Inventories as of March 31, 2000 and December 31, 1999 consist of the following:

	March 31, 2000	December 31, 1999
	----	----
Raw materials	\$ 954	\$ 1,042
Work-in-process	430(1)	165(2)
Finished products	4,257	3,345
	-----	-----
	\$ 5,641	\$ 4,552
	=====	=====

(1) Net of reserves of \$1,160.

(2) Net of reserves of \$675.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2000 and December 31, 1999 consist of the following:

	March 31,	December 31,
	----- 2000 -----	----- 1999 -----
Accounts payable	\$2,051	\$2,642
Accrued payroll and related costs	2,174	1,977
Accrued clinical trial expense	1,414	1,005
Accrued expenses, other	1,048	643
Deferred compensation	234	284
	---	---
	\$6,921	\$6,551
	=====	=====

5. Amgen-Regeneron Partners Research Collaboration Agreement

In August 1990, the Company entered into a collaboration with Amgen Inc. ("Amgen") to develop and commercialize BDNF and neurotrophin-3 ("NT-3"). Pursuant to that agreement, the Company and Amgen formed a partnership, Amgen-Regeneron Partners (the "Partnership"), whereby the revenues earned and expenses incurred by the Partnership for the research and development of BDNF and NT-3 are shared equally. The Company accounts for its investment in the Partnership in accordance with the equity method of accounting.

Selected operating statement data of the Partnership for the three months ended March 31, 2000 and 1999 is as follows:

	Three Months Ended March 31,	
	----- 2000 -----	----- 1999 -----
Total revenues	\$ 78	\$ 116
Total expenses	(2,619)	(2,048)
	-----	-----
Net loss	(\$2,541)	(\$1,932)
	=====	=====

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, 2000 and 1999, the components of comprehensive loss were:

	2000	1999
	-----	-----
Net loss	(\$7,318)	(\$8,930)
Change in net unrealized gain/loss on marketable securities	(23)	(151)
	-----	-----
Total comprehensive loss	(\$7,341)	(\$9,081)
	=====	=====

7. Issuance of Common Stock in a Cashless Exchange

On March 2, 2000, in accordance with the terms of their warrant agreement, as amended, Amgen exercised 700,000 warrants with an exercise price of \$16.00 per share. As consideration for the exercise price, Amgen tendered 221,958 shares of the Company's Common Stock which had an aggregate fair market value at the time of exercise equal to the exercise price of the warrants. The shares of Common Stock delivered to the Company by Amgen were retired upon receipt.

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, 2000 and 1999, the Company reported net losses; 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 (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2000:	Basic and Diluted	(\$7,318)	31,927	(\$0.23)
1999:	Basic and Diluted	(\$8,930)	31,274	(\$0.29)

Options and warrants 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,			
		2000		1999	
		Weighted Average Number, in thousands	Weighted Average Exercise Price	Weighted Average Number, in thousands	Weighted Average Exercise Price
Options and warrants with exercise prices below the average fair market value of the Company's common stock for the respective period		7,442	\$9.42	2,414	\$5.78
Options and warrants with exercise prices above the average fair market value of the Company's common stock for the respective period		102	\$50.14	4,575	\$11.55
Total		7,544		6,989	

9. Segment Reporting

For the period ended March 31, 2000, the Company's operations were 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.

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

Prior to 2000, the Company's operations were all conducted under the research and development business segment. The table below presents information about reported segments for the three months ended March 31, 2000:

	Research & Development -----	Contract Manufacturing -----	Reconciling Items -----	Total -----
Revenues	\$9,122	\$1,376	\$1,226(1)	\$11,724
Loss in Amgen- Regeneron Partners	1,271	-	-	1,271
Depreciation and amortization	926	-(2)	-	926
Interest expense	22	42	-	64
Net (loss) income	(6,827)	(1,717)	1,226	(7,318)
Total assets	15,050	35,837	81,147(3)	132,034

- (1) Represents investment income.
- (2) Depreciation and amortization related to contract manufacturing is capitalized into inventory.
- (3) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

10. Impact of the Adoption of Recently Issued Accounting Standards

In December 1999, the staff of the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin 101, "Revenue Recognition", ("SAB 101"). SAB 101 requires companies who receive license and milestone payments, whether refundable or non-refundable, to recognize them ratably over the period that the related services are rendered.

In the period of adoption, companies will be required to report the cumulative effect of this change in accounting principle as a separate component in net income (or loss). Regeneron is required to adopt SAB 101 during the quarter ending June 30, 2000, and is currently evaluating how to apply SAB 101 and the impact that it will have on the Company's financial statements. Although the effects of SAB 101 cannot be fully determined at this time, the Company estimates that, if SAB 101 had been adopted as of December 31, 1999, the cumulative charge to earnings, and corresponding increase in deferred revenue which will be recognized in future periods, would have been less than \$5 million.

11. Subsequent Event

On April 4, 2000, the Company completed a public offering of 2.6 million shares of Common Stock at a price of \$29.75 per share for proceeds to the Company, before expenses, of \$73.5 million.

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 Regeneron's product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, a variety of items described herein and in the footnotes to Regeneron's financial statements (including the useful life of assets, the anticipated length of agreements, and other matters), and the future uses of capital and financial needs of Regeneron. These statements are made by Regeneron 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.

Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic drugs for the treatment of serious medical conditions. Expanding from our initial focus on degenerative neurologic diseases, we have more recently broadened our product pipeline to include drug candidates for the treatment of obesity, rheumatoid arthritis, cancer, allergies, asthma, ischemia, and other diseases and disorders.

Our ability to discover and develop product candidates for such a wide variety of serious medical conditions results from the leveraging of several powerful technology platforms, many of which were developed or enhanced by us. In contrast to basic genomics approaches, which attempt to identify every gene in a cell or genome, we use Targeted Genomics(TM) and Functionomics(TM) (functional cloning) technology platforms that are designed to discover specific genes of therapeutic interest for a particular disease or cell type. Using these approaches, we have discovered many new families of growth factors and receptors, many of which are already protected by issued patents, and which have led to several product candidates. If the natural protein itself is not a product candidate, we utilize our Designer Protein Therapeutics(TM) platform to genetically engineer product candidates with the desired properties. This technology platform has already produced more than 10 patented proteins, several of which are in preclinical development.

The sophisticated application of all of these technology platforms, coupled with our biologic expertise in preclinical models of disease, has allowed us to discover drug candidates that address a wide variety of important medical needs. We have three products in ongoing clinical trials and several product candidates are expected to enter clinical trials over the next one to two years, including:

- o AXOKINE(R) second generation ciliary neurotrophic factor: Acts on the brain region regulating food intake and energy expenditure. AXOKINE is being developed for the treatment of obesity and complications of obesity such as Type II diabetes, and is in clinical trials. We are also developing a modified form of

AXOKINE (pegylated) that in preclinical studies is substantially longer acting than unmodified AXOKINE. This may allow less frequent and lower dosing in patients.

- o Cytokine Traps: Protein-based antagonists for cytokines such as interleukin-1 (called IL-1), interleukin-4 (IL-4), interleukin-6 (IL-6) and a single antagonist that blocks both IL-4 and interleukin-13 (IL-13). These cytokines are thought to play a major role in diseases such as rheumatoid arthritis and other inflammatory diseases, asthma, allergic disorders, and cancer. Cytokine Traps are potential treatments for these diseases, and at least one Cytokine Trap is expected to enter clinical trials by 2001.
- o VEGF Trap: An antagonist to Vascular Endothelial Growth Factor (called VEGF), which is required for the growth of blood vessels that are needed for tumors to grow. In a preclinical model of cancer, the VEGF Trap blocked the growth of tumors by an anti-angiogenesis mechanism. VEGF Trap is a potential treatment for cancer and is expected to enter clinical trials in 2001.
- o Angiopoietins: A new family of growth factors, discovered by us, that are specific for blood vessels and early hemopoietic stem cells. The Angiopoietins, and engineered forms of these growth factors that can act as activators and blockers, are in preclinical testing for promoting blood vessel growth (to provide blood flow in diseased hearts and other tissues that have lost their original blood supplies), for blocking blood vessel growth (for the treatment of cancers), for fixing leaky blood vessels (that cause swelling and edema in many different diseases such as stroke, diabetic retinopathy, and inflammatory diseases), and for promoting the growth and mobilization of certain hemopoietic cells such as stem cells and platelets.
- o Brain-derived neurotrophic factor, or BDNF: Promotes survival of the spinal cord neurons that die in amyotrophic lateral sclerosis (or ALS, commonly known as Lou Gehrig's Disease) in preclinical models. BDNF is in clinical trials for ALS using two routes of administration; one of these trials is based on the results of a prior Phase III clinical trial.
- o Neurotrophin-3, or NT-3: Acts on the neurons of the intestinal tract, and is in clinical trial for the treatment of constipating disorders associated with spinal cord injury and other neurologic diseases.

Discussion of First Quarter 2000 Activities. In the first quarter of 2000, Regeneron initiated a Phase II dose-ranging trial to study the safety and efficacy of AXOKINE in obese patients. AXOKINE is being developed for the treatment of obesity and complications of obesity such as Type II diabetes. The double-blind, placebo-controlled multicenter clinical trial will be conducted in approximately 175 severely obese patients who will be treated for 90 days at doses up to 2 micrograms per kilogram per day administered subcutaneously. The Phase II study follows a two-week Phase I study, completed in late 1999, in which mildly to moderately obese subjects treated with AXOKINE lost weight and had reduced food intake compared to those on placebo. In the Phase I study, some patients who received higher doses of AXOKINE and who had previously contracted herpes simplex virus (HSV) experienced "cold sores" related to reactivation of their HSV infection. Increased cold sores caused by HSV were also

reported in previous clinical studies of ciliary neurotrophic factor (also called CNTF), AXOKINE's parent molecule. In addition, some patients in the study experienced a reversible and generally asymptomatic increase in pulse rate in a dose-related fashion. The Phase II study of AXOKINE will be conducted at doses that were associated with weight loss, generally well tolerated, and not associated with herpes cold sores in the Phase I study; there will be no restrictions as to a subject's prior history of herpes cold sores. The Phase II study is designed to confirm the weight loss observed in the Phase I study in a trial of longer duration and to determine the lowest effective well-tolerated dose. The Company also plans to collect additional data in the study about the relationship of AXOKINE and reactivation of HSV, about the effect of AXOKINE on pulse rate, and about the possible development of neutralizing antibodies when AXOKINE is administered for a longer time.

Regeneron signed an agreement with Emisphere Technologies, Inc. during the first quarter of 2000 to establish a research and development collaboration to utilize Emisphere's oral drug delivery technology for AXOKINE. In preliminary preclinical pharmacokinetic studies, the Emisphere technology was able to achieve measurable blood levels of AXOKINE. Under the terms of the agreement, Regeneron will support research at Emisphere and under certain conditions will make additional payments, including license and milestone payments. Regeneron will receive exclusive worldwide commercialization rights to oral products that result from the collaboration and pay Emisphere a royalty on sales of any such products.

No assurance can be made regarding the timing or final result of the Phase II study or the timing or result of any further clinical trial of AXOKINE. Previous clinical studies of AXOKINE and CNTF, in addition to weight loss, resulted in the creation of neutralizing antibodies and adverse events (side effects) in patients, including cough, nausea, malaise, and increased herpes simplex cold sores. While certain aspects of the development of AXOKINE have focused on attempting to avoid or minimize antibody production or adverse events, no assurance may be given that these problems will be avoided or minimized or that they will not lead to the failure, delay, or additional difficulty in conducting AXOKINE clinical trials. We discuss the risks associated with antibody development and adverse side effects in the section of this report titled "Factors That May Affect Future Operating Results."

During the first quarter of 2000, Regeneron and The Procter & Gamble Company continued to collaborate in research and development in the fields of angiogenesis, cancer, bone growth and related areas, muscle injury and atrophy, and small molecule (orally active) drugs. The majority of Regeneron's scientific resources are devoted to its collaborative activities with Procter & Gamble.

Regeneron continues to develop, independent of any corporate collaboration, its proprietary Cytokine Traps for the potential treatment of rheumatoid arthritis and other inflammatory diseases, asthma, and allergic disorders.

In the first quarter of 2000, Regeneron entered into a collaboration under a binding memorandum of understanding with Medarex, Inc. to discover, develop and commercialize human antibodies as therapeutics. Regeneron will contribute our expertise in discovering and characterizing proteins as drug discovery targets, and Medarex will contribute its HuMAb-Mouse(TM) technology to create fully human antibody products for those targets. The companies have selected more than twenty initial targets, including growth factors, cytokines, and receptors, and plan to add additional targets in the future. Regeneron and Medarex intend to prioritize targets based upon a variety of

criteria, including target validation, reagent availability, market opportunity, competitive factors, intellectual property position, and the expected feasibility of obtaining antibodies that have the desired properties. The HuMAB-Mouse is a transgenic mouse whose genes for creating mouse antibodies have been inactivated and replaced by human antibody genes. This makes it possible to rapidly create and develop fully human antibodies as drug candidates. Regeneron and Medarex agreed to share preclinical and clinical responsibilities and intend to jointly market any drugs that result from this collaboration.

During the first quarter of 2000, Amgen-Regeneron Partners, the partnership equally owned by Regeneron and Amgen Inc., continued to develop BDNF and NT-3. BDNF is currently being developed by Amgen-Regeneron Partners for potential use in treating ALS through two routes of administration: intrathecal (infusion into the spinal fluid through an implanted pump, supplied by Medtronic, Inc.) and subcutaneous (injection under the skin). In the fourth quarter of 1998, Amgen, on behalf of the partnership began an intrathecal study in more than 200 patients with ALS. Subcutaneous studies conducted by Regeneron on behalf of the partnership began in the first quarter of 1998. The subcutaneous studies are based on an analysis of the Amgen-Regeneron Partners Phase III trial of BDNF for ALS that was completed in 1996. That trial failed to achieve its predetermined end points, but subsequent analyses indicated that a retrospectively-defined subset of ALS patients in the trial may have received a survival benefit from BDNF treatment. A multi-center study of more than 300 ALS patients who will receive BDNF subcutaneously began in August 1999 and is fully enrolled.

Regeneron and Sumitomo Pharmaceuticals Co., Ltd. are collaborating in the development of BDNF in Japan, initially for the treatment of ALS. In March 1998, Sumitomo Pharmaceuticals commenced a Phase I safety assessment of BDNF delivered subcutaneously to normal volunteers and signed a license agreement for the development of BDNF in Japan. Pursuant to the license agreement, Sumitomo Pharmaceuticals made research progress payments to Regeneron of \$5.0 million (reduced by \$0.5 million of Japanese withholding tax) in August 1998 and \$3.0 million (reduced by \$0.3 million of Japanese withholding tax) in April 2000, and will be required to make additional payments upon the achievement of specified milestones. Sumitomo Pharmaceuticals will also pay a royalty on sales of BDNF in Japan.

Amgen-Regeneron Partners' clinical development of NT-3 is currently focused on constipating conditions. In 1998, Regeneron, on behalf of Amgen-Regeneron Partners, completed a small clinical study that included healthy volunteers and patients suffering from severe idiopathic constipation, and began additional small studies that are continuing in 2000 in patients who suffer from constipation associated with conditions such as spinal cord injury and the use of narcotic analgesics. In February 2000, Regeneron initiated a double-blind, placebo-controlled Phase II study in more than 100 patients with functional constipation.

No assurance can be given that extended administration of BDNF or NT-3 will be safe or effective. The treatment of ALS has been shown, in a number of clinical settings using a variety of treatment modalities (including Amgen-Regeneron Partners' earlier clinical studies), to present significant difficulties. The design of an ALS clinical study presents special difficulties and risks, as do the facts that ALS is a progressive disease that afflicts individual patients differently and other ALS treatments are approved or have been or are currently being tested, creating the possibility that patients in any BDNF study may also receive other therapeutics during all or part of the BDNF trial. The treatment of constipating conditions may present additional clinical trial risks in light of the complex and not wholly understood mechanisms of action that lead to the conditions,

the concurrent use of other drugs to treat the underlying illnesses as well as the gastrointestinal condition, the potential difficulty of designing and achieving significant clinical end points, and other factors. No assurance can be given that these or any other studies of BDNF or NT-3 will be successful or that BDNF or NT-3 will be commercialized.

A minority of all research and development programs ultimately result in commercially successful drugs; it is not possible to predict whether any program will succeed until it actually produces a drug that is commercially marketed for a significant period of time. In addition, in each of the areas of Regeneron's independent and collaborative activities, other companies and entities are actively pursuing competitive paths toward similar objectives. The results of the Company'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, BDNF, 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. Regeneron cannot predict whether, when, or under what conditions any of its research or product candidates, including without limitation AXOKINE, BDNF, or NT-3, 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.

Regeneron has not received any revenues from the commercial sale of products and may never receive such revenues. Before such revenues can be realized, Regeneron (or its collaborators) must overcome a number of hurdles which include successfully completing its research and development efforts and obtaining regulatory approval from the FDA or regulatory authorities in other countries. The Company is attempting to develop drugs for human therapeutic use and no assurance can be made that any of the Company's research and development activities will be successful or that any of the Company's current or future potential product candidates will be commercialized. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render Regeneron's products and technologies noncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2000, Regeneron had a cumulative loss of \$207.6 million. In the absence of revenues from commercial product sales or other sources (the amount, timing, nature, or source of which cannot be predicted), Regeneron's losses will continue as it conducts its research and development activities. The Company's activities may expand over time and may require additional resources, and the Company's operating losses may be substantial over at least the next several years. Regeneron's losses may fluctuate from quarter to quarter and will depend, among other factors, on the timing of certain expenses and on the progress of its research and development efforts.

Results of Operations

Three months ended March 31, 2000 and 1999. The Company's total revenue increased to \$11.7 million for the first quarter of 2000 from \$6.9 million for the same period in 1999. Contract research and development revenue increased to \$9.1 million for the first quarter of 2000 from \$3.3 million for the same period in 1999, as revenue from

Procter & Gamble increased to \$7.1 million for the first quarter of 2000 from \$2.9 million for the same period in 1999. Effective in the third quarter of 1999, research support under the Company's collaboration agreement with Procter & Gamble increased from \$1.1 million per quarter to \$7.0 million per quarter. However, Procter & Gamble payments related to AXOKINE research stopped in the third quarter of 1999 after Procter & Gamble returned the product rights to AXOKINE to the Company. Revenue from Amgen-Regeneron Partners increased to \$1.9 million in the first quarter of 2000 from \$0.4 million for the same period in 1999 due to increased clinical trial activity on BDNF and NT-3. Contract manufacturing revenue, related primarily to a long-term manufacturing agreement with Merck & Co., Inc. to manufacture a vaccine intermediate, decreased to \$1.4 million in the first quarter of 2000 from \$2.1 million for the same period in 1999. In the first quarter of 1999, Merck revenue was primarily reimbursement for expenses related to preparing for commercial production, which began in the fourth quarter of 1999. In the first quarter of 2000, Merck revenue was primarily payments related to commercial production. The Company's investment income decreased to \$1.2 million in the first quarter of 2000 from \$1.5 million for the same period in 1999 due primarily to lower levels of interest-bearing investments as the Company funds its operations.

The Company's total operating expenses increased to \$19.0 million in the first quarter of 2000 from \$15.8 million for the same period in 1999. Research and development expenses increased to \$12.0 million in the first quarter of 2000 from \$11.2 million for the same period in 1999, primarily as a result of higher staffing and increased activity in the Company's preclinical and clinical research programs. The loss in Amgen-Regeneron Partners increased to \$1.3 million in the first quarter of 2000 from \$1.0 million for the same period in 1999 due to the partnership's increased clinical trial activity on BDNF and NT-3. Research and development expenses (including loss in Amgen-Regeneron Partners) were approximately 70% of total operating expenses in the first quarter of 2000, compared to 77% for the same period in 1999.

General and administrative expenses increased to \$1.8 million in the first quarter of 2000 from \$1.6 million for the same period of 1999, due primarily to an increase in patent expenses related to foreign filings and higher administrative staffing. Depreciation and amortization expense increased to \$0.9 million in the first quarter of 2000 from \$0.7 million in the first quarter of 1999, resulting from improvements made to the Company's leased facilities in Tarrytown, New York, as well as purchases of new research equipment. Contract manufacturing expenses increased to \$3.1 million in the first quarter of 2000 from \$1.3 million for the same period in 1999 due to costs associated with initiating commercial production at the Company's Rensselaer, New York facility of both vaccine intermediate for Merck and BDNF for clinical use by Sumitomo Pharmaceuticals. Interest expense was \$0.1 million for the first quarter of both 2000 and 1999.

The Company's net loss for the first quarter of 2000 was \$7.3 million, or \$0.23 per share (basic and diluted), compared to a net loss of \$8.9 million, or \$0.29 per share (basic and diluted), for the same period in 1999.

Liquidity and Capital Resources

Since its inception in 1988, the Company has financed its operations primarily through private placements and public offerings of its equity securities, revenue earned

under the agreements between the Company and Amgen, Sumitomo Chemical Company, Ltd., Sumitomo Pharmaceuticals, Merck, and Procter & Gamble, and investment income.

In May 1997, Regeneron and Procter & Gamble entered into the P&G Agreement. Procter & Gamble agreed over the first five years of the P&G Agreement to purchase up to \$60.0 million in Regeneron equity (of which \$42.9 million was purchased in June 1997) and provide up to \$94.7 million in support of Regeneron's research efforts related to the collaboration (of which \$24.0 million was received through March 31, 2000). During the second five years of the P&G Agreement, the companies will share all research costs equally. Clinical testing and commercialization expenses for jointly developed products will generally be shared equally throughout the ten years of the collaboration. The companies expect jointly to develop and market worldwide any products resulting from the collaboration and share equally in profits. Either company may terminate the P&G Agreement at the end of five years with at least one year prior notice or earlier if a defined event of default occurs. Beginning in the third quarter of 1999, research support from Procter & Gamble increased from \$1.1 million per quarter to at least \$6.3 million per quarter through June 2002.

In connection with Regeneron's agreement to collaborate with Sumitomo Pharmaceuticals in the research and development of BDNF in Japan, Sumitomo Pharmaceuticals paid the Company \$25.0 million through December 1997. The Company also received research progress payments from Sumitomo Pharmaceuticals of \$5.0 million (reduced by \$0.5 million of Japanese withholding tax) in August 1998 and \$3.0 million (reduced by \$0.3 million of Japanese withholding tax) in April 2000. In addition, Sumitomo Pharmaceuticals has paid the Company \$27.6 million through March 31, 2000 in connection with supplying BDNF for preclinical and clinical use. Regeneron did not supply any BDNF to Sumitomo Pharmaceuticals in 1999. During the fourth quarter of 1999, Regeneron commenced production of BDNF and began capitalizing manufacturing costs into inventory. The Company expects to resume supplying BDNF to Sumitomo Pharmaceuticals for clinical use in 2000.

The Company's activities relating to BDNF and NT-3, as agreed upon by Amgen and Regeneron, are being reimbursed by Amgen-Regeneron Partners, and the Company recognizes such reimbursement as revenue. The funding of Amgen-Regeneron Partners is through capital contributions from Amgen and Regeneron, who must make equal payments in order to maintain equal ownership and equal sharing of any profits or losses from the partnership. The Company has made capital contributions totaling \$52.7 million to Amgen-Regeneron Partners from the partnership's inception in June 1993 through March 31, 2000. These contributions could increase or decrease, depending upon (among other things) the nature and cost of BDNF and NT-3 studies that Amgen-Regeneron Partners may conduct and the outcomes of those studies.

From its inception in January 1988 through March 31, 2000, the Company invested approximately \$68.3 million in property, plant, and equipment. This includes \$17.3 million to acquire and renovate the Rensselaer facility and an additional \$14.1 million to complete construction at the facility pursuant to the Merck manufacturing agreement. In connection with the purchase and initial renovation of the Rensselaer facility, the Company obtained financing of \$2.0 million from the New York State Urban Development Corporation, of which \$1.6 million is outstanding. Under the terms of this UDC financing, the Company is not permitted to declare or pay dividends on its equity securities.

The Company expects 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 Company is currently involved in interference proceedings in the Patent and Trademark Office between Regeneron's patent applications and patents relating to CNTF issued to Synergen, Inc. Amgen acquired all outstanding shares of Synergen in 1994. In March 1998, the Company and Amgen entered into a covenant not to sue each other which, among other things, provided a simple mechanism for resolving their patent interference and related patent proceedings relating to CNTF and AXOKINE without protracted litigation. The Company also granted Amgen a license to use CNTF and second generation CNTFs other than AXOKINE to treat retinal degenerative conditions. Regeneron will not pay royalties or make other payments to the other party in consideration of this agreement.

As of March 31, 2000, the Company had no established banking arrangements through which it could obtain short-term financing or a line of credit. Additional funds may be raised through, among other things, the issuance of additional securities, other financing arrangements, and future collaboration agreements. No assurance can be given that additional financing will be available or, if available, that it will be available on acceptable terms. In addition, the Company estimates that through mid-2002 it could receive additional payments from Procter & Gamble in the form of research funding and equity purchases of as much as \$90 million or more.

At March 31, 2000, the Company had \$77.9 million in cash, cash equivalents, and marketable securities. On April 4, 2000, Regeneron completed a public offering of 2.6 million shares of Common Stock at a price of \$29.75 per share for proceeds to the Company, before expenses, of \$73.5 million. The Company expects to incur substantial funding requirements for, among other things, research and development activities (including preclinical and clinical testing), validation of manufacturing facilities, and the acquisition of equipment. The Company expects to incur ongoing funding requirements for capital contributions to Amgen-Regeneron Partners to support the continued development and clinical trials of BDNF and NT-3. Through 2000, the Company expects further increases in the level of quarterly research and development expenses as the Company continues to add staff and increases its clinical activity. The amount needed to fund operations will also depend on other factors, including the status of competitive products, the success of the Company's research and development programs, the status of patents and other intellectual property rights developments, and the continuation, extent, and success of any collaborative research programs (including those with Amgen and Procter & Gamble). The Company believes that under its current strategy its existing capital resources will enable it to meet operating needs for several years. No assurance can be given that there will be no change in projected revenues or expenses that would lead to the Company's capital being consumed significantly before such time.

Impact of the Adoption of Recently Issued Accounting Standards

In December 1999, the staff of the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin 101, "Revenue Recognition", ("SAB 101"). SAB 101 requires companies who receive license and milestone payments, whether refundable or non-refundable, to recognize them ratably over the period that the related services are rendered.

In the period of adoption, companies will be required to report the cumulative effect of this change in accounting principle as a separate component in net income (or loss). Regeneron is required to adopt SAB 101 during the quarter ending June 30, 2000, and is currently evaluating how to apply SAB 101 and the impact that it will have on the Company's financial statements. Although the effects of SAB 101 cannot be fully determined at this time, the Company estimates that, if SAB 101 had been adopted as of December 31, 1999, the cumulative charge to earnings, and corresponding increase in deferred revenue which will be recognized in future periods, would have been less than \$5 million.

Factors That May Affect Future Operating Results

Regeneron cautions stockholders and potential investors that the following important factors, among others, in some cases have affected, and in the future could affect, Regeneron's actual results and could cause Regeneron's actual results to differ materially from those expressed in any forward-looking statements made by, or on behalf of, Regeneron. 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:

- o Delay, difficulty, or failure of the Company's research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by the Company or others.
- o Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, those with Procter & Gamble and Amgen) and the resulting loss of research or other funding could have a material adverse effect on the Company and its operations. A change of control of one or more of the Company's material collaborators or licensees could also have a material adverse effect on the Company.
- o Delay, difficulty, or failure of a clinical trial of any of the Company's 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, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol.
- o In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by Regeneron's drug 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

been treated with AXOKINE, BDNF, and NT-3 have developed antibodies, though we have no information that indicates that these antibodies are neutralizing antibodies.

- o Delay, difficulty, or failure in obtaining regulatory approval (including approval of its facilities for production) for the Company's products, including delays or difficulties in development because of insufficient proof of safety or efficacy.
- o Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.
- o Competitive or market factors that may cause use of the Company's products to be limited or otherwise fail to achieve broad acceptance.
- o 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.
- o Difficulties or high costs of obtaining adequate financing to meet the Company's obligations under its collaboration and licensing agreements or to fund 50 percent of the cost of developing product candidates in order to retain 50 percent of the commercialization rights.
- o Amount and rate of growth of Regeneron's general and administrative expenses, and the impact of unusual charges resulting from Regeneron's ongoing evaluation of its business strategies and organizational structure.
- o Failure of corporate partners to develop or commercialize successfully the Company's products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between Regeneron and its corporate partners.
- o 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.
- o Difficulties in obtaining key raw materials and supplies for the manufacture of the Company's product candidates.
- o 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 Regeneron relating to intellectual property rights and licenses; the issuance and use of patents and proprietary technology by Regeneron and its competitors, including the possible negative effect on the Company's ability to develop, manufacture, and sell its products in circumstances where it is unable to obtain licenses to patents which may be required for such products.

- o Underutilization of the Company's 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.
- o Health care reform, including reductions or changes in reimbursement available for prescription medications or other reforms.
- o The ability to attract and retain key personnel.

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

Item 3. Quantitative and Qualitative Disclosure About Market Risk.

The Company's earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from its investment of available cash balances in investment grade corporate and U.S. government securities. The Company does not believe it is materially exposed to changes in interest rates. Under its current policies the Company does not use interest rate derivative instruments to manage exposure to interest rate changes.

PART II. OTHER INFORMATION

ITEM 5. OTHER INFORMATION

William G. Roberts, M.D., who has been Vice President, Regulation Development since May 1999 is the son-in-law of P. Roy Vagelos, M.D., who has been Chairman of the Board of Directors of the Company since January 1995.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

27 Financial Data Schedule

(b) Reports

On March 29, 2000, the Company filed a report on Form 8-K regarding the fact that the Company issued a press release entitled "Regeneron Initiates Phase II Obesity Clinical Trial", a copy of which was included as an exhibit to that filing.

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 12, 2000

By: /s/ Murray A. Goldberg

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

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