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

Form 10-Q

| (X) | (Mark One) QUARTERLY REPORT PURSUANT TO SEC EXCHANGE ACT OF 1934 | TION 13 OR 15(d) OF THE SECURITIES |
|----------------------------------|--|---|
| | For the quarterly period ended | March 31, 1999 |
| | OR | |
| () | TRANSITION REPORT PURSUANT TO SE EXCHANGE ACT OF 1934 | CTION 13 OR 15 (d) OF THE SECURITIES |
| | For the transition period from $_$ | to |
| | Commission File Number 0-190 | |
| | REGENERON PHARMA | CEUTICALS, INC. |
| | (Exact name of registrant as | |
| | New York | 13-3444607 |
| | | (I.R.S. Employer Identification No.) |
| | 77 Old Saw Mill River Road Tarrytown, New York | 10591-6707 |
| | ess of principal executive offices | |
| | (914) 34 | 7-7000 |
| | (Registrant's telephone num | |
| to be fi the pred required | iled by Section 13 or 15(d) of the | rant (1) has filed all reports required Securities Exchange Act of 1934 during ter period that the registrant was as been subject to such filing |
| | Yes X | No |
| | e the number of shares outstanding stock as of April 30, 1999: | of each of the issuer's classes of |
| | Class of Common Stock | Number of Shares |
| | Class A Stock, \$0.001 par value | 3,630,786 27,670,663 |

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REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT MARCH 31, 1999 AND DECEMBER 31, 1998 (Unaudited) (In thousands, except share data)

| ASSETS | March 31, 1999 | December 31, 1998 |
|--|---|---|
| Current assets Cash and cash equivalents Marketable securities Receivable due from The Procter & Gamble Company Receivable due from Merck & Co., Inc. Receivable due from Amgen-Regeneron Partners Receivable due from Sumitomo Pharmaceuticals Company, Ltd. Prepaid expenses and other current assets | \$21,777 46,177 3,555 2,568 590 182 1,340 | \$19,757 66,022 3,169 1,665 709 167 1,412 |
| Total current assets | 76,189 | 92,901 |
| Marketable securities Investment in Amgen-Regeneron Partners Property, plant and equipment, at cost, net of accumulated depreciation and amortization Other assets | 36,617 2,125 34,239 159 | 27,751 3,091 33,019 153 |
| Total assets | \$149,329 ======= | \$156,915 ========== |
| LIABILITIES and STOCKHOLDERS' EQUITY Current liabilities | | |
| Accounts payable and accrued expenses Capital lease obligations, current portion Note payable, current portion Deferred revenue, current portion | \$6,032 1,029 64 2,734 | \$5,551 1,051 65 2,735 |
| Total current liabilities | 9,859 | 9,402 |
| Capital lease obligations Note payable Other liabilities | 1,215 1,594 287 | 1,457 1,609 282 |
| Deferred revenue | 12,938 | 12,938 |
| 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; 3,630,786 shares issued and outstanding in 1999 and 1998 Common Stock, \$.001 par value; 60,000,000 shares authorized; 27,670,663 shares issued and outstanding in 1999 | 4 | 4 |
| 27,386,858 shares issued and outstanding in 1998 | 28 | 27 |
| Additional paid-in capital Unearned compensation | 309,760 (270) | 308,561 (360) |
| Accumulated deficit | (186, 163) | (177, 233) |
| Accumulated other comprehensive income | 77 | 228 |
| Total stockholders' equity | 123,436 | 131,227 |
| Total liabilities and stockholders' equity | \$149,329 ======= | \$156,915 ======== |

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

| | Three months 1999 | ended March 31, 1998 |
|--|---------------------------|---------------------------|
| Revenues | | |
| Contract research and development Contract manufacturing Investment income | \$3,344 2,115 1,459 | \$4,574 1,886 1,790 |
| | 6,918 | 8,250 |
| Expenses | | |
| Research and development | 11,221 | 8,150 |
| Loss in Amgen-Regeneron Partners General and administrative | 966 1,593 | 687 1,384 |
| Depreciation and amortization | 725 | 869 |
| Contract manufacturing | 1,254 | 868 |
| Interest | 89 | 121 |
| | 15,848 | 12,079 |
| Net loss | (\$8,930) ====== | (\$3,829) ====== |
| Net loss per share, basic and diluted | (\$0.29) | (\$0.12) |

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, 1999
(In thousands)

| | Class A Stock | | Common Sto | ock |
|--|---|--------------------------------|--|------------------------|
| | Shares | Amount | Shares | Amount |
| Balance, December 31, 1998 | 3,631 | \$4 | | \$27 |
| Amortization of unearned compensation Issuance of Common Stock in connection with exercise of stock options Issuance of Common Stock in connection | | | 246 | 1 |
| with Company 401(k) Savings Plan contribution Net loss Change in net unrealized gain on marketable securities | | | 38 | |
| Balance, March 31, 1999 | 3,631 | \$4 | 27,671 ========= | \$28 |
| | Additional Paid-in Capital | | nearned pensation | Accumulated Deficit |
| Balance, December 31, 1998 | \$308,5 | 661 | (\$360) | (\$177,233) |
| Amortization of unearned compensation Issuance of Common Stock in connection with exercise of stock options Issuance of Common Stock in connection | 8 | 991 | 90 | |
| with Company 401(k) Savings Plan contribution Net loss | 3 | 308 | | (8,930) |
| Change in net unrealized gain on marketable securities | | | | |
| Balance, March 31, 1999 | \$309,7 | '60 | ====================================== | (\$186,163) |
| | | | | |
| | Other Com | nulated nprehensive come | Total Stockholders' Equity | Comprehensive Loss |
| Balance, December 31, 1998 | | \$228 | \$131,227 | |
| Amortization of unearned compensation Issuance of Common Stock in connection | | | 90 | |
| with exercise of stock options Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | | 892 308 | |
| Net loss Change in net unrealized gain | | | (8,930) | (\$8,930) |
| on marketable securities | | (151) | (151) | (151) |
| Balance, March 31, 1999 | ======================================= | \$77 | \$123,436 | (\$9,081) |

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

Three months ended March 31, 1999 1998 Cash flows from operating activities Net loss (\$8,930)(\$3,829) Adjustments to reconcile net loss to net cash used in operating activities Loss in Amgen-Regeneron Partners 966 687 Depreciation and amortization 725 869 Stock issued in consideration for services rendered 90 90 Changes in assets and liabilities (Increase) decrease in amounts due from The Procter & Gamble Company (386) 97 Increase in amounts due from Merck & Co., Inc. (903) (189) Decrease (increase) in amounts due from Amgen-Regeneron Partners 119 (73) (Increase) decrease in amounts due from Sumitomo Pharmaceuticals Co., Ltd. 2,115 (15)Increase in investment in Amgen-Regeneron Partners (1,030)66 (741) Decrease (increase) in prepaid expenses and other assets Decrease in deferred revenue (1) (1,750)Decrease in accounts payable, accrued expenses, and other liabilities (158)(452)Total adjustments 503 (377)Net cash used in operating activities (8,427)(4,206)Cash flows from investing activities Purchases of marketable securities (22,857)(26,475)Sales of marketable securities 33,685 22,342 Capital expenditures (993) (874) Net cash provided by (used in) investing activities 9,835 (5,007) Cash flows from financing activities Net proceeds from the issuance of stock 892 317 Principal payments on note payable (16)(17)Capital lease payments (264)(750)Net cash provided by (used in) financing activities 612 (450) 2,020 Net increase (decrease) in cash and cash equivalents (9,663)

19,757

\$21,777 ======== 28,921

\$19,258

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

Cash and cash equivalents at beginning of period

Cash and cash equivalents at end of period

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 operation, 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. 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, 1998.

2. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 1999 and December 31, 1998 were approximately \$1,421 and \$469, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 1998 and December 31, 1997 were approximately \$117 and \$635, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 1998 was approximately \$308 of accrued Company 401(k) Savings Plan contribution expense. During January 1999 the Company contributed approximately thirty-eight thousand shares of Common Stock to the 401(k) Savings Plan in satisfaction of this obligation.

Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 1999 and December 31, 1998 consist of the following:

| | March 31, 1999 | December 31, 1998 |
|--|-------------------|----------------------|
| Accounts payable | \$3,044 | \$2,223 |
| Accrued payroll and related costs Accrued clinical trial expense | 1,507 775 | 1,346 1,336 |
| Accrued expenses, other | 419 | 359 |
| Deferred compensation | 287 | 287 |
| | \$6,032 | \$5,551 |
| | ===== | ===== |

4. Amgen-Regeneron Partners Research Collaboration Agreement

In August 1990, the Company and Amgen Inc. 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, 1999 and 1998 are as follows:

| | Three Months | Ended March 31, |
|----------------------------------|---------------------|---------------------|
| | 1999 | 1998 |
| Total revenues Total expenses | \$ 116 (2,048) | \$ 40 (1,413) |
| Net loss | (\$1,932) ====== | (\$1,373) ====== |

5. 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. The comprehensive loss for the three months ended March 31, 1999 has been included in the Statement of Stockholders' Equity. For the three months ended March 31, 1999 and 1998, the components of comprehensive loss were:

| Total comprehensive loss | (\$9,081) ====== | (\$3,868) ====== |
|--|---------------------|---------------------|
| | | |
| Change in net unrealized gain on marketable securities | (151) | (39) |
| Net loss | (\$8,930) | (\$3,829) |
| | | |
| | 1999 | 1998 |

6. 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, 1999 and 1998, 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 (Denominator) | Per Share Amount | |
| 1999: | | | | |
| Basic and Diluted | (\$8,930) | 31,274 | (\$0.29) | |
| 1998: | | | | |
| Basic and Diluted | (\$3,829) | 30,932 | (\$0.12) | |

Options and warrants which have been excluded from the diluted per share amounts because their effect would have been antidilutive include the following: $\frac{1}{2} \int_{-\infty}^{\infty} \frac{1}{2} \left(\frac{1}{2} \int_{-\infty}^{\infty} \frac{1}{2} \left($

| | Three Months Ended March 31, | | | |
|---|-------------------------------|---------------------------------------|-------------------------------|---------------------------------------|
| | 1999 | | 1998 | |
| | Weighted Average Number | Weighted Average Exercise Price | Weighted Average Number | 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 | 2,414 | \$5.78 | 1,848 | \$4.61 |
| Options and warrants with exercise prices above the average fair market value of the Company's common stock for the respective period | 4,575 | \$11.55 | 4,433 | \$11.72 |
| Total | 6,989 ===== | | 6,281 ===== | |

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. ("Regeneron" or the "Company") and actual events or results may differ materially. These statements concern, among other things, the possible therapeutic applications of the Company's product candidates and research programs, the timing and nature of the Company's clinical and research programs now underway or planned, a variety of items described herein and in the footnotes to the Company'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 the Company. These statements are made by the Company 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 is a leader in the application of molecular and cell biology to discover novel potential therapeutics for human medical conditions and is seeking to develop and commercialize these discoveries. The Company is applying its technological expertise in protein growth factors, their receptors, and their mechanisms of action to the discovery and development of protein-based drugs and orally active, small molecule drugs.

The Company is pursuing research and development programs in the following areas:

- AXOKINE(Registered) second generation ciliary neurotrophic factor for the treatment of Type II diabetes in obese patients and uncomplicated obesity.
- o Brain-derived neurotrophic factor ("BDNF") for the treatment of amyotrophic lateral sclerosis ("ALS," commonly known as Lou Gehrig's disease),
- o Neurotrophin-3 ("NT-3") for the treatment of constipating conditions,
- o Angiogenesis, including stimulating blood vessel growth in settings where more blood flow is desired and blocking blood vessel growth in abnormal conditions such as cancer. The angiogenesis program is based on Regeneron's discovery of Angiopoietins, a new family of ligands (and their receptors, called the TIE family of receptors) that appears to regulate blood vessel formation,
- o Protein antagonists for cytokines such as interleukin-1 ("IL-1"), interleukin-4 ("IL-4") and interleukin-6 ("IL-6") as potential treatment of inflammatory diseases, allergic disorders, and cancer,
- AXOKINE for the treatment of retinal diseases such as retinitis pigmentosa,
- o Muscle atrophy, using a variety of approaches to identify and validate drug targets, and

o Research programs to discover orally active, small molecule-based drugs, some of which may mimic or antagonize protein- or receptor-based drug candidates that the Company is developing.

Discussion of First Quarter 1999 Activities. In the first quarter of 1999, the Company continued to develop AXOKINE under the Company's collaboration agreement ("the P&G Agreement") with The Procter & Gamble Company ("Procter & Gamble"). The Company and Procter & Gamble filed an Investigational New Drug application ("IND") with the United States Food and Drug Administration ("FDA") in the first quarter of 1999 and commenced a Phase I clinical study to determine the safety of AXOKINE administered subcutaneously for a short duration to mildly to moderately obese healthy volunteers. AXOKINE is being developed for the treatment of Type II diabetes in obese patients and uncomplicated obesity. No assurance can be made regarding the timing or result of this or any further clinical trial of AXOKINE. AXOKINE has never been administered to people. Its safety and efficacy in the treatment of any human condition have not been established and can not be predicted. Previous clinical studies of ciliary neurotrophic factor ("CNTF"), the parent molecule of AXOKINE, resulted in the creation of antibodies and adverse events (side effects) in patients, including weight loss, cough, nausea, and malaise. While certain aspects of the development of AXOKINE by the Company and Procter & Gamble 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.

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

The Company continued independently to develop AXOKINE for use in treating retinitis pigmentosa.

During the first quarter of 1999, the Company continued to develop independent of any corporate collaboration its proprietary cytokine traps for the potential treatment of asthma, inflammatory disease, cancer, and rheumatoid arthritis. In addition, the Company continued to conduct research with Pharmacopeia, Inc. in the area of small molecule (orally active) drugs.

During the first quarter of 1999, Amgen-Regeneron Partners, the partnership equally owned by Regeneron and Amgen Inc. ("Amgen"), 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) 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 200 ALS patients who will receive BDNF subcutaneously is expected to begin later in 1999.

The Company and Sumitomo Pharmaceuticals Co., Ltd. ("Sumitomo Pharmaceuticals") 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. In August 1998, Sumitomo Pharmaceuticals signed a license agreement for the development of BDNF in Japan. Pursuant to the license agreement, Sumitomo Pharmaceuticals made a \$5.0 million research progress payment (reduced by \$0.5 million of Japanese withholding tax) to Regeneron in August 1998 and will be required to make additional payments upon the achievement of specified milestones. Sumitomo Pharmaceuticals will also be required to 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 continued through the first quarter of 1999 in patients who suffer from constipation associated with conditions such as spinal cord injury and Parkinson's disease.

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.

Substantial risk is inherent in the research, development, and commercialization of drugs. In addition, in each of the areas of the Company'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, 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. The Company 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 the Company's product candidates to treat human conditions or to be approved for marketing could have a material adverse impact on the Company.

To date, Regeneron has not received any revenues from the commercial sale of products and may never receive such revenues. Before such revenues can be realized, the Company (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. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render the Company's products and technologies noncompetitive and obsolete.

From inception on January 8, 1988 through March 31, 1999, Regeneron had a cumulative loss of \$186.2 million. In the absence of revenues from commercial product sales or other sources (the amount, timing, nature, or source of which cannot be predicted), the Company's losses will continue as the Company 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. The Company'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 the Company's research and development efforts.

Results of Operations

Three months ended March 31, 1999 and 1998. The Company's total revenue decreased to \$6.9 million for the first quarter of 1999 from \$8.3 million for the same period in 1998. Contract research and development revenue decreased to \$3.3 million for the first quarter of 1999 from \$4.6 million for the same period in 1998. The Company earned higher contract research and development revenue related to the P&G Agreement in the first quarter of 1999 versus the same period in 1998. This was more than offset by nominal revenue in the first quarter of 1999 from the Company's ongoing collaboration with Sumitomo Pharmaceuticals, versus revenue of \$1.8 million for the same period in 1998, as revenue from research payments under the Company's collaboration agreement with Sumitomo Pharmaceuticals ended in 1998, and because the Company did not supply any BDNF to Sumitomo Pharmaceuticals for preclinical and clinical use in the first quarter of 1999. Contract manufacturing revenue related to the Company's 1995 manufacturing agreement (the "Merck Agreement") with Merck & Co., Inc. ("Merck") increased to \$2.1 million for the first quarter of 1999 compared to \$1.9 million for the same period in 1998 as a result of increased activity in preparation for manufacturing a product for Merck at the Company's Rensselaer facility. The Company's investment income decreased to \$1.5 million in the first quarter of 1999 from \$1.8 million for the same period in 1998 due primarily to lower levels of interest-bearing investments as the Company funds its operations.

The Company's total operating expenses increased to \$15.8 million in the first quarter of 1999 from \$12.1 million for the same period in 1998. Research and development expenses increased to \$11.2 million in the first quarter of 1999 from \$8.2 million for the same period in 1998, primarily as a result of higher staffing and increased activity in the Company's preclinical and clinical research programs. The Company's share of the loss in Amgen-Regeneron Partners increased to \$1.0 million in the first quarter of 1999 from \$0.7 million for the same period in 1998 as a result of the partnership's increased clinical trial activity on BDNF and NT-3. Research and development expenses (including loss in Amgen-Regeneron Partners) were approximately 77% of total operating expenses in the first quarter of 1999, compared to 73% for the same period in 1998.

General and administrative expenses increased to \$1.6 million in the first quarter of 1999 from \$1.4 million for the same period of 1998, primarily to support the Company's increased research and development and manufacturing activities. Depreciation and amortization expense decreased to \$0.7 million in the first quarter of 1999 from \$0.9 million in the first quarter of 1998, as certain laboratory equipment and leasehold improvements became fully depreciated. Contract manufacturing expenses, which are expenses directly related to the Merck Agreement and are reimbursed by Merck, increased to \$1.3 million in the first quarter of 1999 from \$0.9 million in the same period of 1998, primarily due to increased activity in preparation for manufacturing a product for Merck. Interest expense was \$0.1 million for the first quarter of both 1999 and 1998.

The Company's net loss for the first quarter of 1999 was \$8.9 million, or \$0.29 per share (basic and diluted), compared to a net loss of \$3.8 million, or \$0.12 per share (basic and diluted), for the same period in 1998.

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

In May 1997, the Company 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 \$7.7 million was received through March 31, 1999). 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. In September 1997, the Company and Procter & Gamble expanded the P&G Agreement to include AXOKINE and related molecules (delivered systemically), and agreed to develop AXOKINE initially to treat obesity associated with Type II diabetes. Procter & Gamble agreed to reimburse the Company for certain research and development costs and pay as much as \$15.0 million in additional funding, partly subject to achieving certain milestones related to AXOKINE. Of the \$15.0 million, \$5.0 million was paid in 1997 and \$5.0 million was paid in 1998. Beginning in the third quarter of 1999, research support provided from Procter & Gamble, in addition to amounts paid to support development of AXOKINE (which vary from quarter to quarter), will increase from the current rate of \$1.1 million per quarter to at least \$6.3 million per quarter for the following three years of the companies' collaboration agreement.

In connection with the Company'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 a \$5.0 million research progress payment from Sumitomo Pharmaceuticals (reduced by \$0.5 million of Japanese withholding tax) in August 1998. In addition, Sumitomo Pharmaceuticals has paid the Company \$27.4 million through March 31, 1999 in connection with supplying BDNF for preclinical and clinical use. Regeneron expects to resume supplying BDNF to Sumitomo Pharmaceuticals later in 1999.

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 approximately \$50.4 million to Amgen-Regeneron Partners from the partnership's inception in June 1993 through March 31, 1999. The Company expects that its capital contributions in 1999 will total at least \$3.0 million for the full year. 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, 1999, the Company invested approximately \$61.6 million in property, plant, and equipment. This includes \$16.8 million to acquire and renovate the Rensselaer facility and an additional \$14.1 million to complete construction at the facility pursuant to the Merck Agreement. In connection with the purchase and renovation of the Rensselaer facility, the Company obtained financing of \$2.0 million from the New York State Urban Development Corporation, of which \$1.7 million is outstanding. Under the terms of such 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. ("Synergen"). 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, resolved their patent interference and related patent proceedings relating to CNTF and AXOKINE. The Company also granted Amgen a license to use CNTF and second generation CNTFs other than AXOKINE to treat retinal degenerative conditions. Neither party will pay royalties or make other payments to the other party in consideration of this agreement.

As of March 31, 1999, 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, milestones, and equity purchases of as much as \$100 million or more.

At March 31, 1999, the Company had \$104.6 million in cash, cash equivalents, and marketable securities. 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. In 1999, 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 its existing capital resources will enable it to meet operating needs for at least 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.

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, the creation of antibodies (in the case of protein-based therapeutics) that weaken or neutralize the effect of the product candidate (and possibly could have other adverse effects on patients), the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol.

- Delay, difficulty, or failure in obtaining regulatory approval (including approval of its facilities for production) for the Company's products (including vaccine intermediate for Merck), 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 the Company and such corporate partners.
- o Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology products in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.
- o Difficulties in obtaining key raw materials and supplies for the manufacture of the Company's product candidates.
- 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 (into orally active, small molecule pharmaceuticals) and outside of treatments for neurological and neurodegenerative conditions (into, for example, potential programs in obesity, diabetes, cancer, inflammation, muscle disease, bone growth disorders, and angiogenesis), the Company will require additional internal expertise or external collaborations in areas in which it currently does not have substantial resources and personnel.

The Company is evaluating its operations to determine the impact, if any, that Year 2000 problems may have. The Year 2000 problem results from computer programs and devices that do not differentiate between the year 1900 and the year 2000 because they were written using two digits rather than four to define the applicable year. Accordingly, computer systems that have time-sensitive calculations may not properly recognize the year 2000. Like many corporations, Regeneron does not have any previous experience with an issue like the Year 2000 problem.

The Year 2000 problem could affect Regeneron's ability to conduct its normal operations that are date sensitive or depend on computers or equipment that contain embedded chips that are date sensitive. It could adversely affect Regeneron's ability to maintain or operate its facilities in a safe and effective manner or undertake other activities necessary and customary to carrying out its business. In addition, the Year 2000 problem could have material adverse effects on the operations or financial condition of the Company's licensees, licensors, collaborators, suppliers, vendors, and others, and, in particular, utility companies that provide energy to the Company's facilities and equipment, which could, in turn, have a material direct or indirect effect on Regeneron.

The Company's Year 2000 review includes its computer systems and software, embedded systems in non-computer equipment, and vendor operations. The Company has appointed a Year 2000 task force with representatives from each department of the Company and has retained independent consultants to facilitate its review. To date, the Company has not learned of any material Year 2000 issue with respect to its computer systems and software. The Company is in the process of analyzing its laboratory and manufacturing equipment with embedded systems. This analysis is incomplete. The Company is also in the process of surveying its vendors who support critical business processes to determine their level of readiness with respect to Year 2000 issues. While many vendors indicate that they believe they are or will be Year 2000 compliant, many others state that they can not represent that they have achieved compliance or guarantee the efficacy of their remediation efforts. Many vendors state that the problem is too complex for such a claim to have legitimacy; that efforts to solve Year 2000 problems are merely in the nature of risk mitigation; and that success in such efforts will be measured, with hindsight, by the minimization of the level of technical failures and by the prompt identification and repair of failures.

The analysis of the Company's embedded systems and the information collected regarding vendor readiness will be used to formulate a contingency plan with respect to reasonably identifiable items of equipment and supply of materials that are critical to the Company's operations. These analyses and plans are not complete. No assurance can be made that the Company's computer systems and software, embedded systems in non-computer equipment, and vendors will be Year 2000 compliant in a timely or cost-effective manner. The failure of certain third parties (such as Procter & Gamble, Amgen, Sumitomo Pharmaceuticals, Merck, and utility and communications companies) to operate in a normal and customary manner and to maintain Year 2000 compliance (or to assure that their vendors and suppliers are Year 2000 compliant) could have a material adverse effect on the operations and financial condition of Regeneron. It is possible that Regeneron could be adversely affected by the failure of other third parties to be year 2000 compliant even though these third parties do not directly conduct business with Regeneron. It is not possible to guarantee that the Company's Year 2000 contingency plan will succeed or be timely.

The costs of addressing Year 2000 issues have been minor to date, but may increase if substantial consultant or personnel resources are required or if operationally-critical equipment must be remediated or replaced, or if back-up energy sources must be secured (assuming such personnel, equipment, or back-up energy sources are reasonably available). Because the Company's analysis of Year 2000 issues is incomplete, at this time management cannot estimate the total expected costs of the Year 2000 problem. The risks that Year 2000 problems could present to the Company include, without limitation, disruption, delay, or cessation of manufacturing or other operations, including operations that are subject to regulatory compliance, and loss of research and manufacturing material and experiments that are difficult, costly, or impossible to replace. In each case, the correction of the problem could result in substantial expense and disruption or delay of the Company's operations.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

27 Financial Data Schedule

(b) Reports

No reports on Form 8-K were filed by the Registrant during the quarter ended March 31, 1999.

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 14, 1999 By: /s/ Murray A. Goldberg

/s/ Murray A. Goldberg

Murray A. Goldberg

Vice President, Finance &
Administration, Chief
Financial Officer, and
Treasurer

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Regeneron Pharmaceuticals, Inc.
March 31, 1999 Form 100
(in thousands except per share data)
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JAN-01-1999
MAR-31-1999
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