

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 June 30, 1998

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 August 10, 1998:

| Class of Common Stock | Number of Shares |
|----------------------------------|------------------|
| ----- | ----- |
| Class A Stock, \$0.001 par value | 3,639,625 |
| Common Stock, \$0.001 par value | 27,374,769 |

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT JUNE 30, 1998 AND DECEMBER 31, 1997 (Unaudited)
(In thousands, except share data)

| ASSETS | June 30, 1998 ---- | December 31, 1997 ---- |
|--|--------------------------|------------------------------|
| Current assets | | |
| Cash and cash equivalents | \$22,538 | \$28,921 |
| Marketable securities | 52,453 | 63,602 |
| Receivable due from The Procter & Gamble Company | 9,782 | 2,403 |
| Receivable due from Merck & Co., Inc. | 1,290 | 1,707 |
| Receivable due from Amgen-Regeneron Partners | 474 | 356 |
| Receivable due from Sumitomo Pharmaceuticals Co., Ltd. | 935 | 2,115 |
| Prepaid expenses and other current assets | 926 | 536 |
| | ----- | ----- |
| Total current assets | 88,398 | 99,640 |
| Marketable securities | 42,431 | 35,518 |
| Investment in Amgen-Regeneron Partners | 1,914 | 364 |
| Property, plant and equipment, at cost, net of accumulated depreciation and amortization | 32,160 | 32,713 |
| Other assets | 216 | 145 |
| | ----- | ----- |
| Total assets | \$165,119 | \$168,380 |
| | ===== | ===== |
| LIABILITIES and STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | \$5,079 | \$4,663 |
| Capital lease obligations, current portion | 1,157 | 1,770 |
| Note payable, current portion | 72 | 73 |
| Deferred revenue, current portion | 2,205 | 4,182 |
| | ----- | ----- |
| Total current liabilities | 8,513 | 10,688 |
| Capital lease obligations | 1,961 | 2,077 |
| Note payable | 1,640 | 1,675 |
| Other liabilities | 262 | 242 |
| Deferred revenue | 14,971 | 14,801 |
| 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; 3,643,720 shares issued and outstanding in 1998 | | |
| 4,117,540 shares issued and outstanding in 1997 | 4 | 4 |
| Common Stock, \$.001 par value; 60,000,000 shares authorized; 27,363,854 shares issued and outstanding in 1998 | | |
| 26,804,941 shares issued and outstanding in 1997 | 27 | 27 |
| Additional paid-in capital | 308,516 | 308,109 |
| Unearned compensation | (540) | (720) |
| Accumulated deficit | (170,297) | (168,608) |
| Accumulated other comprehensive income | 62 | 85 |
| | ----- | ----- |
| Total stockholders' equity | 137,772 | 138,897 |
| | ----- | ----- |
| Total liabilities and stockholders' equity | \$165,119 | \$168,380 |
| | ===== | ===== |

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 June 30, | | Six months ended June 30, | |
|---|-----------------------------|-----------|---------------------------|------------|
| | 1998 | 1997 | 1998 | 1997 |
| | ----- | ----- | ----- | ----- |
| Revenues | | | | |
| Contract research and development | \$6,202 | \$4,377 | \$10,776 | \$8,616 |
| Research progress payments | 5,000 | | 5,000 | |
| Contract manufacturing | 2,281 | 858 | 4,167 | 1,555 |
| Investment income | 1,712 | 1,381 | 3,502 | 2,659 |
| | ----- | ----- | ----- | ----- |
| | 15,195 | 6,616 | 23,445 | 12,830 |
| | ----- | ----- | ----- | ----- |
| Expenses | | | | |
| Research and development | 9,054 | 6,881 | 17,204 | 13,957 |
| Loss in Amgen-Regeneron Partners | 186 | 479 | 873 | 2,179 |
| General and administrative | 1,693 | 1,688 | 3,077 | 3,152 |
| Depreciation and amortization | 780 | 1,165 | 1,649 | 2,367 |
| Contract manufacturing | 1,235 | 476 | 2,103 | 969 |
| Interest | 107 | 197 | 228 | 405 |
| | ----- | ----- | ----- | ----- |
| | 13,055 | 10,886 | 25,134 | 23,029 |
| | ----- | ----- | ----- | ----- |
| Net income (loss) | \$2,140 | (\$4,270) | (\$1,689) | (\$10,199) |
| | ===== | ===== | ===== | ===== |
| Net income (loss) per share, basic and diluted | \$0.07 | (\$0.16) | (\$0.05) | (\$0.38) |
| | ===== | ===== | ===== | ===== |

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

REGENERON PHARMACEUTICALS, INC.
 CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
 For the six months ended June 30, 1998
 (In thousands)

| | Class A Stock | | Common Stock | | Additional Paid-in Capital | Unearned Compensation |
|---|---------------|--------|--------------|--------|----------------------------------|--------------------------|
| | Shares | Amount | Shares | Amount | | |
| Balance, December 31, 1997 | 4,118 | \$4 | 26,805 | \$27 | \$308,109 | (\$720) |
| Amortization of unearned compensation | | | | | | 180 |
| Issuance of Common Stock in connection with exercise of stock options | | | 85 | | 407 | |
| Conversion of Class A Stock to Common Stock | (474) | | 474 | | | |
| Net loss | | | | | | |
| Change in net unrealized gain on marketable securities | | | | | | |
| Balance, June 30, 1998 | 3,644 | \$4 | 27,364 | \$27 | \$308,516 | (\$540) |

| | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders' Equity | Comprehensive Loss |
|---|------------------------|--|----------------------------------|-----------------------|
| | | | | |
| Balance, December 31, 1997 | (\$168,608) | \$85 | \$138,897 | |
| Amortization of unearned compensation | | | 180 | |
| Issuance of Common Stock in connection with exercise of stock options | | | 407 | |
| Conversion of Class A Stock to Common Stock | | | | |
| Net loss | (1,689) | | (1,689) | (\$1,689) |
| Change in net unrealized gain on marketable securities | | (23) | (23) | (23) |
| Balance, June 30, 1998 | (\$170,297) | \$62 | \$137,772 | (\$1,712) |

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)

| | Six months ended June 30, 1998 | 1997 |
|--|-----------------------------------|------------|
| | ---- | ---- |
| Cash flows from operating activities | | |
| Net loss | (\$1,689) | (\$10,199) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Loss in Amgen-Regeneron Partners | 873 | 2,179 |
| Depreciation and amortization | 1,649 | 2,367 |
| Stock issued in consideration for services rendered | 180 | 180 |
| Changes in assets and liabilities | | |
| Increase in amounts due from The Procter & Gamble Company | (7,379) | (938) |
| Decrease (increase) in amounts due from Merck & Co., Inc. | 417 | (98) |
| Increase in amounts due from Amgen-Regeneron Partners | (118) | (359) |
| Decrease (increase) in amounts due from Sumitomo Pharmaceuticals Co., Ltd. | 1,180 | (255) |
| Increase in investment in Amgen-Regeneron Partners | (2,423) | (9) |
| (Increase) decrease in prepaid expenses and other assets | (461) | 221 |
| Decrease in deferred revenue | (1,807) | (925) |
| Increase in accounts payable, accrued expenses, and other liabilities | 881 | 371 |
| Total adjustments | (7,008) | 2,734 |
| Net cash used in operating activities | (8,697) | (7,465) |
| Cash flows from investing activities | | |
| Purchases of marketable securities | (43,883) | (46,078) |
| Sales of marketable securities | 48,096 | 30,440 |
| Capital expenditures | (1,090) | (1,085) |
| Net cash provided by (used in) investing activities | 3,123 | (16,723) |
| Cash flows from financing activities | | |
| Net proceeds from the issuance of stock | 407 | 43,207 |
| Principal payments on note payable | (36) | (38) |
| Capital lease payments | (1,180) | (2,011) |
| Net cash (used in) provided by financing activities | (809) | 41,158 |
| Net (decrease) increase in cash and cash equivalents | (6,383) | 16,970 |
| Cash and cash equivalents at beginning of period | 28,921 | 34,475 |
| Cash and cash equivalents at end of period | \$22,538 | \$51,445 |

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 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, 1997.

2. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Capital lease obligations of \$451 and \$619 were incurred during the first six months of 1998 and 1997, respectively, when the Company leased new equipment.

Included in accounts payable and accrued expenses at June 30, 1998 and December 31, 1997 were approximately \$190 and \$635, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 1997 and December 31, 1996 were approximately \$1,127 and \$800, respectively, of accrued capital expenditures. In addition, approximately \$40 of costs incurred in connection with the Company's issuance of equity securities were included in accounts payable and accrued expenses at June 30, 1997.

3. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 1998 and December 31, 1997 consist of the following:

| | June 30, 1998 ---- | December 31, 1997 ---- |
|-----------------------------------|--------------------------|------------------------------|
| Accounts payable | \$2,439 | \$2,947 |
| Accrued payroll and related costs | 1,343 | 654 |
| Accrued clinical trial expense | 320 | 320 |
| Accrued expenses, other | 690 | 392 |
| Deferred compensation | 287 | 350 |
| | ----- | ----- |
| | \$5,079 | \$4,663 |
| | ===== | ===== |

4. Income Taxes

For the three months ended June 30, 1998, the Company did not record a provision for income taxes. The Company was able to apply net operating loss carry-forwards against its taxable net income, and the effect of the alternative minimum tax was not material.

5. 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 income statement data of the Partnership for the three and six months ended June 30, 1998 and 1997 are as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|----------------|-----------------------------|---------|---------------------------|-----------|
| | 1998 | 1997 | 1998 | 1997 |
| Total revenues | \$43 | \$37 | \$83 | \$187 |
| Total expenses | (416) | (995) | (1,829) | (4,546) |
| Net loss | (\$373) | (\$958) | (\$1,746) | (\$4,359) |

6. Earnings per Share

The Company's basic net income (loss) per share amounts have been computed by dividing net income (loss) by the weighted average number of Common and Class A shares outstanding. For the three months ended June 30, 1998, the Company reported net income; therefore, common stock equivalents were included in the computation of diluted net income per share. For the three months ended June 30, 1997 and for the six months ended June 30, 1998 and 1997, 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 income (loss) per share are as follows:

| Three Months Ended June 30, | | | |
|-------------------------------|----------------------------------|-------------------------|--------------------------------|
| | Net Income (Loss) (Numerator) | Shares (Denominator) | Net Income (Loss) Per Share |
| 1998: | | | |
| Basic | \$2,140 | 31,003 | \$0.07 |
| Effect of dilutive securities | | | |
| Options | -- | 985 | -- |
| Diluted | \$2,140 | 31,988 | \$0.07 |
| 1997: | | | |
| Basic and diluted | (\$4,270) | 27,193 | (\$0.16) |

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 June 30, | | | | |
|---|-------------------------------|--|-------------------------------|--|
| | 1998 | | 1997 | |
| | Weighted Average Number | Weighted Average Exercise Price | Weighted Average Number | Weighted Average Exercise Price |
| Options with exercise prices below the average fair market value of the Company's common stock for the respective period | | | 1,890 | \$4.49 |
| Options and warrants with exercise prices above the average fair market value of the Company's common stock for the respective period | 4,002 | \$12.05 | 2,495 | \$13.34 |
| Total | 4,002 | | 4,385 | |

6. Earnings per Share (continued)

| Six Months Ended June 30, | | | |
|---------------------------|-------------------------|-------------------------|---------------------|
| | Net Loss (Numerator) | Shares (Denominator) | Per Share Amount |
| 1998: | | | |
| Basic and Diluted | (\$1,689) | 30,968 | (\$0.05) |
| 1997: | | | |
| Basic and Diluted | (\$10,199) | 26,496 | (\$0.38) |

Options and warrants, which have been excluded from the diluted per share amounts because their effect would have been antidilutive include the following:

| | Six Months Ended June 30, | | | |
|---|--|---|--|---|
| | 1998 | | 1997 | |
| | 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 | 2,328 | \$5.43 | 2,298 | \$5.40 |
| Options and warrants with exercise prices above the average fair market value of the Company's common stock for the respective period | 4,010 | \$12.04 | 1,831 | \$14.64 |
| Total | 6,338 ===== | | 4,129 ===== | |

7. Adoption of Statement of Financial Accounting Standards No. 130

The Company has adopted Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income ("SFAS No. 130"). 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 disclosures required by SFAS No. 130 for the six months ended June 30, 1998 have been included in the Statement of Stockholders' Equity. For the six months ended June 30, 1998 and 1997, the components of comprehensive loss were:

| | 1998 | 1997 |
|---|------------|------------|
| | ---- | ---- |
| Net loss | (\$ 1,689) | (\$10,199) |
| Change in net unrealized gain on marketable securities | (23) | (136) |
| | ----- | ----- |
| Total comprehensive loss | (\$1,712) | (\$10,335) |
| | ===== | ===== |

8. Impact of the Future Adoption of Recently Issued Accounting Standard

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, Accounting for Derivative and Hedging Activities ("SFAS No. 133"). SFAS No. 133 establishes a comprehensive standard on accounting for derivatives and hedging activities and is effective for periods beginning after June 15, 1999. Management does not believe that the future adoption of SFAS No. 133 will have a material effect on the Company's financial position and results of operations.

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:

- o AXOKINE(R), a second generation ciliary neurotrophic factor, for the treatment of obesity associated with Type II diabetes and possibly for uncomplicated obesity,
- o AXOKINE for the treatment of retinitis pigmentosa and other retinal diseases,
- 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 enteric neuropathies (constipating conditions),
- o Angiopoietins, a new family of ligands (and their receptors, called the TIE family of receptors) that appears to regulate blood vessel formation, or angiogenesis,
- o Protein antagonists for cytokines such as interleukin-4 ("IL-4") and interleukin-6 ("IL-6") as potential treatment of inflammatory diseases, allergic disorders, and cancer,
- o Noggin, a naturally occurring protein, for potential use in treating abnormal bone formation and related diseases and conditions,
- o Muscle atrophy, that occurs in a variety of clinical settings following disuse or denervation of muscle, 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 Second Quarter 1998 Activities. In the second quarter of 1998, the Company continued to develop AXOKINE under the Company's collaboration agreement ("the P&G Agreement") with The Procter and Gamble Company ("Procter & Gamble"). The Company and Procter & Gamble plan to file an Investigational New Drug application ("IND") with the United States Food and Drug Administration ("FDA") in early 1999 in order to conduct early stage clinical studies of AXOKINE for the treatment of obesity associated with Type II diabetes and possibly for uncomplicated obesity. No assurance can be made regarding the timing or nature of such IND in light of the need successfully to complete substantial preclinical development activities, the timing of which is partially not in the control of the Company or Procter & Gamble, before filing an IND. In addition, no assurance can be made regarding the timing, nature, or result of any clinical trial of AXOKINE. AXOKINE has never been administered to people. Its safety and efficacy to treat any 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, malaise, and others. 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.

In June 1998, the Company and Procter & Gamble executed a development agreement for AXOKINE and other potential drug candidates which resulted in a \$5.0 million research progress payment to the Company from Procter & Gamble. The Company and Procter & Gamble also continued to collaborate in research and development in the fields of angiogenesis, bone growth, and muscle injury and atrophy, as well as 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 degenerative retinal diseases. The Company is collaborating with academic investigators, government agencies, and private foundations in the development of AXOKINE for retinal disease. Subject to completion of appropriate preclinical experiments and regulatory approval, the Company plans to commence a Phase I clinical study of AXOKINE to treat retinitis pigmentosa in early 1999. In July 1998, the Company and Medtronic, Inc. terminated their 1996 collaborative development agreement to conduct an exploratory research program using Medtronic delivery systems to deliver AXOKINE to the central nervous system, initially as a potential treatment for Huntington's disease, due to obstacles in formulation and delivery.

During the second quarter of 1998, the Company continued to develop independent of any corporate collaboration its proprietary cytokine traps for the potential treatment of inflammatory disease, asthma, cancer, and rheumatoid arthritis. In addition, the Company continued to conduct research with Pharmacoepia, Inc. and Glaxo Wellcome plc in the area of small molecule (orally active) drugs.

During the second quarter of 1998, 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). Amgen, on behalf of Amgen-Regeneron Partners, has completed a Phase I safety study of BDNF delivered intrathecally and is planning to begin a Phase II clinical trial later this year. 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.

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 initiated a Phase I clinical trial in Japan to assess the safety 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 is expected to make a \$5.0 million milestone payment to Regeneron in the third quarter of 1998 and will 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 enteric neuropathies (constipating conditions). The enteric nervous system is a complex collection of nerves that control the function of the gastrointestinal system, including gastrointestinal motility. In June 1998, Regeneron, on behalf of Amgen-Regeneron Partners, began the first of a series of small clinical studies of NT-3 in enteric neuropathies. The initial study includes patients suffering from severe idiopathic constipation. Later studies may be in patients who suffer from constipation associated with Parkinson's disease, spinal cord injury, use of opiate pain-killers, and other conditions.

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 various 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, and NT-3 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 June 30, 1998, Regeneron had a cumulative loss of \$170.3 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 June 30, 1998 and 1997. The Company's total revenue increased to \$15.2 million for the second quarter of 1998 from \$6.6 million for the same period in 1997. Contract research and development revenue increased to \$6.2 million for the second quarter of 1998 from \$4.4 million for the same period in 1997, as higher revenue related to the P&G Agreement more than offset a decrease in revenue from Sumitomo Pharmaceuticals. A research progress payment of \$5.0 million was received in the second quarter of 1998 from Procter & Gamble in connection with a collaboration to develop AXOKINE for obesity associated with Type II diabetes and possibly for uncomplicated obesity. Contract manufacturing revenue related to the long-term manufacturing agreement (the "Merck Agreement") with Merck & Co., Inc. ("Merck") increased to \$2.3 million for the second quarter of 1998 compared to \$0.9 million for the same period in 1997 as a result of increased activity in preparation for manufacturing a product for Merck at the Company's Rensselaer facility. Investment income in the second quarter of 1998 increased to \$1.7 million from \$1.4 million for the same period in 1997, due mainly to higher levels of interest-bearing investments resulting primarily from

the proceeds of a private placement of equity securities with Procter & Gamble in June 1997.

The Company's total operating expenses increased to \$13.1 million in the second quarter 1998 from \$10.9 million for the same period in 1997. Research and development expenses increased to \$9.1 million in the second quarter of 1998 from \$6.9 million for the same period in 1997, primarily as a result of additional employees and increased activity in the Company's preclinical and clinical research programs. Loss in Amgen-Regeneron Partners decreased to \$0.2 million in the second quarter of 1998 from \$0.5 million for the same period in 1997, as the level of research activity declined. Research and development expenses (including loss in Amgen-Regeneron Partners) were approximately 71% of total operating expenses in the second quarter of 1998, compared to 68% for the same period in 1997.

General and administrative expenses were \$1.7 million in both the second quarters of 1998 and 1997. Depreciation and amortization expense decreased to \$0.8 million in the second quarter of 1998 from \$1.2 million in the second quarter of 1997, as certain laboratory equipment and leasehold improvements became fully depreciated. Contract manufacturing expenses, which are direct expenses related to the Merck Agreement and are reimbursed by Merck, increased to \$1.2 million in the second quarter of 1998 from \$0.5 million in the same period of 1997, primarily due to increased activity in preparation for manufacturing a product for Merck. Interest expense decreased to \$0.1 million from \$0.2 million in the second quarters of 1998 and 1997, respectively, as the amount of outstanding obligations in connection with capital leases declined.

The Company's net income for the second quarter of 1998 was \$2.1 million, or \$0.07 per share (basic and diluted), compared to a net loss of \$4.3 million, or \$0.16 per share (basic and diluted), for the same period in 1997.

Six months ended June 30, 1998 and 1997. The Company's total revenue increased to \$23.4 million for the six months ended June 30, 1998 from \$12.8 million for the same period in 1997. Contract research and development revenue increased to \$10.8 million for the six months ended June 30, 1998 from \$8.6 million for the same period in 1997, as higher revenue related to the P&G Agreement more than offset a decrease in revenue from Sumitomo Pharmaceuticals. A research progress payment of \$5.0 million was received in the second quarter of 1998 from Procter & Gamble in connection with a collaboration to develop AXOKINE for obesity associated with Type II diabetes and possibly for uncomplicated obesity. Contract manufacturing revenue related to the Merck Agreement increased to \$4.2 million for the first six months of 1998 compared to \$1.6 million for the same period in 1997 as a result of increased activity in preparation for manufacturing a product for Merck at the Company's Rensselaer facility. Investment income for the six months ended June 30, 1998 increased to \$3.5 million from \$2.7 million for the same period in 1997, due mainly to higher levels of interest-bearing investments resulting primarily from the proceeds of a private placement of equity securities with Procter & Gamble in June 1997.

The Company's total operating expenses increased to \$25.1 million for the six months ended June 30, 1998 from \$23.0 million for the same period in 1997. Research and development expenses increased to \$17.2 million in the first six months of 1998 from \$14.0 million for the same period in 1997, primarily as a result of additional employees and increased activity in the Company's preclinical and clinical research programs. Loss in Amgen-Regeneron Partners decreased to \$0.9 million in the first half of 1998 from \$2.2 million for the same period in 1997, as the level of research activity declined.

Research and development expenses (including loss in Amgen-Regeneron Partners) were approximately 72% of total operating expenses in the first six months of 1998, compared to 70% for the same period in 1997.

General and administrative expenses decreased slightly to \$3.1 million for the six months ended June 30, 1998 from \$3.2 million for the same period in 1997. Depreciation and amortization expense decreased to \$1.6 million for the six months ended June 30, 1998 from \$2.4 million for the same period in 1997, as certain laboratory equipment and leasehold improvements became fully depreciated. Contract manufacturing expenses, which are direct expenses related to the Merck Agreement and are reimbursed by Merck, increased to \$2.1 million in the first half of 1998 from \$1.0 million in the same period of 1997, primarily due to increased activity in preparation for manufacturing a product for Merck. Interest expense decreased to \$0.2 million from \$0.4 million for the six months ended June 30, 1998 and 1997, respectively, as the amount of outstanding obligations in connection with capital leases declined.

The Company's net loss for the six months ended June 30, 1998 was \$1.7 million, or \$0.05 per share (basic and diluted), compared to a net loss of \$10.2 million, or \$0.38 per share (basic and diluted), for the same period in 1997.

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. 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 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 in the event of a default (as defined in the P&G Agreement). 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 July 1998.

In connection with the Company's agreement to collaborate with Sumitomo Pharmaceuticals in the research and development of BDNF in Japan, the Company continues to be reimbursed in connection with supplying Sumitomo Pharmaceuticals with BDNF for preclinical and clinical use. The Company also expects to receive a \$5.0 million milestone payment from Sumitomo Pharmaceuticals in the third quarter of 1998.

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 \$47.6 million to Amgen-Regeneron Partners from the partnership's inception in June 1993 through June 30, 1998. The Company expects that its capital contributions in 1998 will total \$5.7 million for the full year, of which \$2.4 million has been funded through June 1998. These contributions could increase or decrease, depending upon the cost of Amgen-Regeneron Partners' conducting additional BDNF and NT-3 studies and the outcomes of those and other ongoing studies.

From its inception in January 1988 through June 30, 1998, the Company invested approximately \$57.4 million in property, plant, and equipment. This includes \$16.8 million to acquire and renovate the Rensselaer facility and \$14.1 million of completed construction at the facility related 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 to its stockholders.

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 ciliary neurotrophic factor ("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 opposition and other 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 June 30, 1998, 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 June 30, 1998, the Company had \$117.4 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. 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.
- o 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.
- 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 (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, Year 2000 issues may have. The Company's 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 operation of the Company and has retained independent consultants to facilitate its review. To date, the Company believes that no material Year 2000 issue exists 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 to determine their level of readiness with respect to Year 2000 issues. 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. 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-important equipment must be remediated or replaced. The risks that Year 2000 issues 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. In each case the correction of the problem could result in substantial expense and disruption or delay of the Company's operations.

Impact of the Future Adoption of Recently Issued Accounting Standard

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, Accounting for Derivative and Hedging Activities ("SFAS No. 133"). SFAS No. 133 establishes a comprehensive standard on accounting for derivatives and hedging activities and is effective for periods beginning after June 15, 1999. Management does not believe that the future adoption of SFAS No. 133 will have a material effect on the Company's financial position and results of operations.

PART II. OTHER INFORMATION

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On June 12, 1998, the Company conducted its Annual Meeting of Shareholders pursuant to due notice. A quorum being present either in person or by proxy, the shareholders voted on the following matters:

1. To elect three Directors to hold office for a three-year term as Class I directors and until their successors are duly elected and qualified.

2. To approve the selection of Coopers & Lybrand L.L.P. as independent accountants for the Company's fiscal year ending December 31, 1998.

No other matters were voted on. The number of votes cast was:

| | For --- | Withhold Authority ----- |
|-----------------------------------|------------|--------------------------------|
| 1. Election of Class I Directors | | |
| Leonard S. Schleifer, M.D., Ph.D. | 52,390,382 | 277,081 |
| Eric M. Shooter, Ph.D. | 52,397,662 | 269,801 |
| Fred A. Middleton | 52,397,662 | 269,801 |

The terms of office of P. Roy Vagelos, M.D., Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., Michael S. Brown, M.D., George Sing, and Charles A. Baker continued after the meeting.

| | For --- | Against ----- | Abstain ----- |
|-----------------------------|------------|------------------|------------------|
| 2. Selection of accountants | 52,608,041 | 38,480 | 20,942 |

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 June 30, 1998.

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: August 14, 1998

By: /s/ Murray A. Goldberg

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

| | | |
|-------------|---------|----|
| | 6-MOS | |
| DEC-31-1998 | | |
| JAN-01-1998 | | |
| JUN-30-1998 | | |
| | 22,538 | |
| | 94,884 | |
| | 12,481 | |
| | 0 | |
| | 0 | |
| | 88,398 | |
| | 60,464 | |
| | 28,304 | |
| | 165,119 | |
| 8,513 | | 0 |
| 0 | | 0 |
| | 0 | 31 |
| | 137,741 | |
| 165,119 | | 0 |
| | 23,445 | 0 |
| | 0 | 0 |
| | 24,906 | |
| | 0 | |
| | 228 | |
| | (1,689) | 0 |
| (1,689) | | 0 |
| | 0 | |
| | 0 | 0 |
| | (1,689) | |
| | (0.05) | |
| | (0.05) | |