

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 September 30, 2000  
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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  
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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 October 31, 2000:

<u>Class of Common Stock</u> -----	<u>Number of Shares</u> -----
Class A Stock, \$0.001 par value	2,759,095
Common Stock, \$0.001 par value	34,000,189

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PART I. FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.  
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2000 AND DECEMBER 31, 1999 (Unaudited)  
(In thousands, except share data)

	September 30, 2000	December 31, 1999
	-----	-----
ASSETS		
Current assets		
Cash and cash equivalents	\$49,642	\$23,697
Marketable securities	67,386	42,463
Receivable due from The Procter & Gamble Company	6,907	
Receivable due from Merck & Co., Inc.	360	
Receivable due from Amgen-Regeneron Partners	2,126	473
Receivable due from Sumitomo Pharmaceuticals Company, Ltd.	458	151
Prepaid expenses and other current assets	1,942	1,708
Inventory	8,181	4,552
	-----	-----
Total current assets	137,002	73,044
Marketable securities	41,471	27,439
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	37,659	36,298
Other assets	187	218
	-----	-----
Total assets	\$216,319	\$136,999
	=====	=====
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$8,021	\$6,551
Deferred revenue, current portion	3,782	4,686
Due to Merck & Co., Inc.		334
Due to Amgen-Regeneron Partners	113	300
Capital lease obligations, current portion	759	1,380
Note payable, current portion	67	68
	-----	-----
Total current liabilities	12,742	13,319
Deferred revenue	10,135	11,130
Capital lease obligations	694	1,204
Note payable	1,483	1,527
Other liabilities	293	287
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized;		
2,759,095 shares issued and outstanding in 2000		
3,605,133 shares issued and outstanding in 1999	3	4
Common Stock, \$.001 par value; 60,000,000 shares authorized;		
33,995,109 shares issued and outstanding in 2000		
27,817,636 shares issued and outstanding in 1999	34	28
Additional paid-in capital	404,916	310,296
Accumulated deficit	(213,779)	(200,303)
Accumulated other comprehensive loss	(202)	(493)
	-----	-----
Total stockholders' equity	190,972	109,532
	-----	-----
Total liabilities and stockholders' equity	\$216,319	\$136,999
	=====	=====

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2000	1999	2000	1999
<b>Revenues</b>				
Contract research and development	\$8,783	\$8,570	\$27,043	\$15,311
Research progress payments	3,500		6,200	
Contract manufacturing	2,623	2,730	6,617	7,299
Investment income	2,530	1,236	5,967	4,014
	-----	-----	-----	-----
	17,436	12,536	45,827	26,624
	-----	-----	-----	-----
<b>Expenses</b>				
Research and development	14,085	12,924	40,470	34,963
Loss in Amgen-Regeneron Partners	1,099	952	3,450	2,509
General and administrative	1,737	1,578	5,203	4,691
Depreciation and amortization	1,154	898	3,125	2,452
Contract manufacturing	2,512	1,034	6,828	3,452
Interest	60	75	227	245
	-----	-----	-----	-----
	20,647	17,461	59,303	48,312
	-----	-----	-----	-----
<b>Net loss</b>	<b>(\$3,211)</b>	<b>(\$4,925)</b>	<b>(\$13,476)</b>	<b>(\$21,688)</b>
	=====	=====	=====	=====
<b>Net loss per share, basic and diluted</b>	<b>(\$0.09)</b>	<b>(\$0.16)</b>	<b>(\$0.39)</b>	<b>(\$0.69)</b>
	=====	=====	=====	=====

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

REGENERON PHARMACEUTICALS, INC.  
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)  
For the nine months ended September 30, 2000 (In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	
Balance, December 31, 1999	3,605	\$4	27,818	\$28	\$310,296
Issuance of Common Stock in a public offering at \$29.75 per share			2,600	3	77,347
Cost associated with issuance of equity securities					(4,496)
Issuance of Common Stock in connection with exercise of stock options			686	1	4,283
Net issuance of Common Stock to Amgen Inc. in connection with a cashless exercise of warrants			478		
Issuance of Common Stock to The Procter & Gamble Company			574		17,066
Net issuance of Common Stock to The Procter & Gamble Company in connection with a cashless exercise of warrants			939	1	(1)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			54		421
Conversion of Class A Stock to Common Stock	(846)	(1)	846	1	
Net loss					
Change in net unrealized loss on marketable securities					
Balance, September 30, 2000	2,759	\$3	33,995	\$34	\$404,916

	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	-----	-----	-----	-----
Balance, December 31, 1999	(\$200,303)	(\$493)	\$109,532	
Issuance of Common Stock in a public offering at \$29.75 per share			77,350	
Cost associated with issuance of equity securities			(4,496)	
Issuance of Common Stock in connection with exercise of stock options			4,284	
Net issuance of Common Stock to Amgen Inc. in connection with a cashless exercise of warrants				
Issuance of Common Stock to The Procter & Gamble Company			17,066	
Net issuance of Common Stock to The Procter & Gamble Company in connection with a cashless exercise of warrants				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			421	
Conversion of Class A Stock to Common Stock				
Net loss	(13,476)		(13,476)	(\$13,476)
Change in net unrealized loss on marketable securities		291	291	291
	-----	-----	-----	-----
Balance, September 30, 2000	(\$213,779)	(\$202)	\$190,972	(\$13,185)
	=====	=====	=====	=====

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)

	Nine months ended 2000	September 30, 1999
Cash flows from operating activities		
Net loss	(\$13,476)	(\$21,688)
Adjustments to reconcile net loss to net cash used in operating activities		
Loss in Amgen-Regeneron Partners	3,450	2,509
Depreciation and amortization	3,125	2,452
Stock issued in consideration for services rendered		270
Changes in assets and liabilities		
Increase in amounts due from The Procter & Gamble Company	(6,907)	(4,637)
(Increase) decrease in amounts due from Merck & Co., Inc.	(694)	915
(Increase) decrease in amounts due from Amgen-Regeneron Partners	(1,653)	709
(Increase) decrease in amounts due from Sumitomo Pharmaceuticals Co., Ltd.	(307)	67
Increase in investment in Amgen-Regeneron Partners	(3,637)	(768)
Increase in prepaid expenses and other assets	(1,254)	(300)
Increase in inventory	(2,494)	
Decrease in deferred revenue	(1,899)	(1)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	1,606	(322)
Total adjustments	(10,664)	894
Net cash used in operating activities	(24,140)	(20,794)
Cash flows from investing activities		
Purchases of marketable securities	(75,517)	(45,134)
Sales of marketable securities	37,904	74,437
Capital expenditures	(5,330)	(4,883)
Net cash (used in) provided by investing activities	(42,943)	24,420
Cash flows from financing activities		
Net proceeds from the issuance of stock	94,204	972
Principal payments on note payable	(45)	(48)
Capital lease payments	(1,131)	(782)
Net cash provided by financing activities	93,028	142
Net increase in cash and cash equivalents	25,945	3,768
Cash and cash equivalents at beginning of period	23,697	19,757
Cash and cash equivalents at end of period	\$49,642	\$23,525

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

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 1999 Condensed Balance Sheet data was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 1999.

2. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2000 and December 31, 1999 are \$988 and \$697, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 1999 and December 31, 1998 are \$95 and \$469, respectively, of accrued capital expenditures.

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

3. Inventories

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

Inventories as of September 30, 2000 and December 31, 1999 consist of the following:

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

	September 30, 2000	December 31, 1999
Raw materials	\$1,009	\$1,042
Work-in-process	497(1)	165(3)
Finished products	6,675(2)	3,345
	-----	-----
	\$8,181	\$4,552
	=====	=====

(1) Net of reserves of \$207.

(2) Net of reserves of \$365.

(3) Net of reserves of \$675.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2000 and December 31, 1999 consist of the following:

	September 30, 2000	December 31, 1999
Accounts payable	\$2,164	\$2,642
Accrued payroll and related costs	2,481	1,977
Accrued clinical trial expense	1,737	1,005
Accrued expenses, other	1,423	643
Deferred compensation	216	284
	-----	-----
	\$8,021	\$6,551
	=====	=====

5. Amgen-Regeneron Partners Research Collaboration Agreement

In August 1990, the Company entered into a collaboration with Amgen Inc. ("Amgen") to develop and commercialize BDNF and neurotrophin-3 ("NT-3"). Pursuant to that agreement, the Company and Amgen formed a partnership, Amgen-Regeneron Partners (the "Partnership"). 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 and nine months ended September 30, 2000 and 1999 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2000	1999	2000	1999
Total revenues	\$ 96	\$ 89	\$ 260	\$ 295
Total expenses	(2,295)	(1,992)	(7,160)	(5,312)
	-----	-----	-----	-----
Net loss	(\$2,199)	(\$1,903)	(\$6,900)	(\$5,017)
	=====	=====	=====	=====

6. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the nine months ended September 30, 2000 and 1999, the components of comprehensive loss are:

	2000 -----	1999 -----
Net loss	(\$13,476)	(\$21,688)
Change in net unrealized gain/loss on marketable securities	291	(562)
	-----	-----
Total comprehensive loss	(\$13,185)	(\$22,250)
	=====	=====

7. Equity Transactions

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

On April 4, 2000, the Company completed a public offering of 2.6 million shares of Common Stock at a price of \$29.75 per share for net proceeds, after commissions and expenses, of \$72.9 million.

On August 3, 2000, the Company sold 573,630 shares of Common Stock to The Procter & Gamble Company ("P&G") at a price of \$29.75 per share for total proceeds of \$17.1 million in cash. The \$29.75 price was the same price per share as in Regeneron's public offering of 2.6 million shares of Common Stock in April 2000. The sale of stock was made pursuant to a 1997 securities purchase agreement between Regeneron and P&G. In addition, in accordance with the terms of a 1997 warrant agreement between Regeneron and P&G, as amended, P&G exercised 1,450,000 warrants with an exercise price of \$9.87 per share. As consideration for the exercise price, P&G tendered 511,125 shares of the Company's Common Stock which had an aggregate value at the time of exercise, based upon the average market price of the Company's Common Stock over approximately the prior 30 trading days, equal to the aggregate exercise price of the warrants. The net result of this transaction was that P&G acquired an additional 938,875 shares of Common Stock. The 511,125 shares of Common Stock delivered to the Company by P&G were retired upon receipt.

8. Collaboration Agreement with The Procter and Gamble Company

On August 3, 2000, the Company and P&G agreed through a binding memorandum of understanding to enter into a new collaboration agreement, replacing the companies' 1997 collaboration agreement. The new agreement will extend P&G's obligation to fund Regeneron's research under the new collaboration agreement through December 2005, with no further research obligations by either party thereafter, and focus the companies' collaborative research on therapeutic areas that are of particular interest to P&G, including muscle atrophy and muscle diseases, fibrotic diseases, and certain G-protein coupled receptors. Under the new agreement, P&G's research funding from July 2000 through December 2005 is expected to total approximately \$64 million (before adjustments for future inflation). Any drugs that result from the collaboration will be jointly developed and marketed worldwide, with the companies equally sharing development costs and profits. P&G and the Company have divided rights to programs from the 1997 collaboration agreement that are no longer part of the companies' collaboration.

9. 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 and nine months ended September 30, 2000 and 1999, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

Three Months Ended September 30,			
	Net Loss (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2000:			
Basic and Diluted	(\$3,211)	36,134	(\$0.09)
1999:			
Basic and Diluted	(\$4,925)	31,314	(\$0.16)

Nine Months Ended September 30,			
	Net Loss (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2000:			
Basic and Diluted	(\$13,476)	34,344	(\$0.39)
1999:			
Basic and Diluted	(\$21,688)	31,297	(\$0.69)

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 September 30,		Nine months ended September 30,	
	2000	1999	2000	1999
Weighted Average Number, in thousands	6,480	7,166	7,057	7,089
Weighted Average Exercise Price	\$12.31	\$9.46	\$11.65	\$9.48

10. Long-Term Incentive Plan

In April 2000, the Company adopted the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"). The 2000 Incentive Plan provides for the issuance of up to 6,000,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Board of Directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Options are awards in which Participants receive the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant.

Shares of Restricted Stock may be awarded to Participants at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). The holder of the Restricted Shares has the right to vote and receive dividends during the vesting period. Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the shares will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Shares of Phantom Stock provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests.

Stock Bonuses are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

The 2000 Incentive Plan allows the Committee to provide for immediate vesting of awards upon a change in control of the Company, as defined.

The Company may incur charges to operations in connection with these awards.

11. Segment Reporting

Beginning in 2000, the Company's operations are principally managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of potential therapeutics for human medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to the development of manufacturing processes prior to commencing commercial production of a product.

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

Prior to 2000, the Company's operations were all conducted under the research and development business segment. The table below presents information about reported segments for the three and nine months ended September 30, 2000:

	Three Months Ended September 30, 2000			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
	-----	-----	-----	-----
Revenues	\$12,283	\$2,623	\$2,530 (1)	\$17,436
Loss in Amgen- Regeneron Partners	1,099	-	-	1,099
Depreciation and amortization	1,154	- (2)	-	1,154
Interest expense	42	18	-	60
Net (loss) income	(5,834)	93	2,530	(3,211)

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

		Nine Months Ended September 30, 2000		
	Research & Development	Contract Manufacturing	Reconciling Items	Total
	-----	-----	-----	-----
Revenues	\$33,243	\$6,617	\$5,967 (1)	\$45,827
Loss in Amgen- Regeneron Partners	3,450	-	-	3,450
Depreciation and amortization	3,125	- (2)	-	3,125
Interest expense	153	74	-	227
Net (loss) income	(19,158)	(285)	5,967	(13,476)
Total assets	\$17,677	\$38,014	\$160,628 (3)	\$216,319

(1) Represents investment income.

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

(3) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

12. Impact of the Adoption of Recently Issued Accounting Standards

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

In the period of adoption, companies will be required to report the cumulative effect of this change in accounting principle as a separate component in net income (or loss). Regeneron is required to adopt SAB 101 during the quarter ended December 31, 2000, and is currently evaluating how to apply SAB 101 and the impact that it will have on the Company's financial statements. Although the effects of SAB 101 cannot be fully determined at this time, the Company estimates that, if SAB 101 had been adopted as of September 30, 2000, the cumulative charge to earnings, and corresponding increase in deferred revenue which will be recognized in future periods, would have been less than \$6 million.

In March 2000, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation ("FIN 44"). FIN 44 interprets the provisions of APB Opinion No. 25 that provide guidance on how companies should account for stock compensation granted to employees and is effective for periods beginning on and after July 1, 2000. Management does not believe that the adoption of FIN 44 will have a material effect on the Company's financial position and results of operations.

13. Subsequent Event

On October 31, 2000, Amgen and Regeneron entered into an agreement whereby Regeneron acquired Amgen's patents and patent applications relating to ciliary neurotrophic factor ("CNTF") and related molecules for \$1.0 million. Regeneron then granted back to Amgen exclusive, royalty free rights under these patents and patent applications solely for human ophthalmic uses. In addition, Regeneron entered into a covenant not to sue Amgen under Regeneron's patents and patent applications relating to CNTF and related molecules solely for human ophthalmic uses.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### General

Overview. The discussion below contains forward-looking statements that involve risks and uncertainties relating to the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible therapeutic applications of Regeneron's product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, a variety of items described herein and in the footnotes to Regeneron's financial statements (including the useful life of assets, the anticipated length of agreements, and other matters), and the future uses of capital and financial needs of Regeneron. These statements are made by Regeneron based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Factors That May Affect Future Operating Results" which could cause actual results to differ materially from those indicated by such forward-looking statements.

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

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

The sophisticated application of all of these technology platforms, coupled with our biologic expertise in preclinical models of disease, has allowed us to discover drug candidates that address a wide variety of important medical needs. We have three

products in ongoing clinical trials and several product candidates are expected to enter clinical trials over the next one to two years, including:

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

Discussion of Third Quarter 2000 Activities. In the third quarter of 2000, Regeneron continued its Phase II dose-ranging trial to study the safety and efficacy of AXOKINE in obese patients. AXOKINE is being developed for the treatment of obesity and complications of obesity such as Type II diabetes. The double-blind, placebo-controlled multicenter clinical trial enrolled over 175 severely obese patients. Patients in the trial are being treated for 90 days at doses up to 2 micrograms per kilogram per day administered subcutaneously. The trial is expected to be completed by the end of 2000. The Phase II study follows a two-week Phase I study, completed in late 1999, in which mildly to moderately obese subjects treated with AXOKINE lost weight and had reduced food intake compared to those on placebo. In the Phase I study, some patients who received higher doses of AXOKINE and who had previously contracted herpes simplex virus (HSV) experienced "cold sores" related to reactivation of their HSV infection. Increased cold sores caused by HSV were also reported in previous clinical studies of ciliary neurotrophic factor (also called CNTF), AXOKINE's parent molecule. In addition, some patients in the study experienced a reversible and generally asymptomatic increase in pulse rate in a dose-related fashion. The Phase II study of AXOKINE is being conducted at doses that were associated with weight loss, generally well tolerated, and not associated with herpes cold sores in the Phase I study; there are no restrictions as to a subject's prior history of herpes cold sores. The Phase II study is designed to confirm the weight loss observed in the Phase I study in a trial of longer duration and to determine the lowest effective well-tolerated dose. The Company also plans to collect additional data in the study about the relationship of AXOKINE and reactivation of HSV, about the effect of AXOKINE on pulse rate, and about the possible development of neutralizing antibodies when AXOKINE is administered for a prolonged period of time.

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

During the third quarter of 2000, Regeneron and The Procter & Gamble Company continued to collaborate in research and development under a long-term collaboration agreement. On August 3, 2000, Procter & Gamble made two non-recurring research progress payments to Regeneron totaling \$3.5 million. In addition, on August 3, 2000, Procter & Gamble and Regeneron agreed through a binding memorandum of understanding to enter into a new collaboration agreement, replacing the companies' 1997 collaboration agreement. The new agreement will extend Procter & Gamble's obligation to fund Regeneron's research under the new collaboration agreement through December 2005, with no further research obligations by either party thereafter, and focus

the companies' collaborative research on therapeutic areas that are of particular interest to Procter & Gamble, including muscle atrophy and muscle diseases, fibrotic diseases, and certain G-protein coupled receptors. Under the new agreement, Procter & Gamble's research funding from July 2000 through December 2005 is expected to total approximately \$64 million (before adjustments for future inflation). Any drugs that result from the collaboration will continue to be jointly developed and marketed worldwide, with the companies equally sharing development costs and profits.

Procter & Gamble and Regeneron have divided rights to the programs that are no longer part of the companies' collaboration. Procter & Gamble has obtained rights to certain specified research programs. Regeneron has rights to all other research programs, including exclusive rights to the VEGF Trap, the Angiopoietins, and the RORs. Regeneron expects to begin clinical trials of the VEGF Trap as a potential treatment for cancer in 2001. Regeneron is conducting research on the Angiopoietins, and engineered forms of these growth factors, for promoting the growth of blood vessels (to provide blood flow in diseased hearts and other tissues that have lost their original blood supplies), for the blocking of blood vessel growth (for the treatment of cancers), for fixing leaky blood vessels (that cause swelling and edema in diseases such as stroke, diabetic retinopathy, and inflammatory diseases), and for promoting the growth and mobilization of certain hemopoietic cells (such as stem cells and platelets). The Company is conducting research on the RORs, a growth factor receptor system discovered by Regeneron scientists that is selectively expressed by cartilage cells, for potential use in cartilage diseases such as osteoarthritis.

Regeneron continues to develop, independent of any corporate collaboration, its proprietary Cytokine Traps for the potential treatment of rheumatoid arthritis and other inflammatory diseases, asthma, and allergic disorders. The Company expects to initiate a Phase I clinical study of IL-1 for the treatment of rheumatoid arthritis by the end of 2000 or early 2001.

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

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

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

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

A minority of all research and development programs ultimately result in commercially successful drugs; it is not possible to predict whether any program will succeed until it actually produces a drug that is commercially marketed for a significant period of time. In addition, in each of the areas of Regeneron's independent and collaborative activities, other companies and entities are actively pursuing competitive paths toward similar objectives. The results of the Company's and its collaborators' past activities in connection with the research and development of AXOKINE, Cytokine Traps, Angiopoietins, cancer, abnormal bone growth, muscle atrophy, small molecules, BDNF, NT-3, and other programs or areas of research or development do not necessarily predict the results or success of current or future activities including, but not limited to,

any additional preclinical or clinical studies. Regeneron cannot predict whether, when, or under what conditions any of its research or product candidates, including without limitation AXOKINE, BDNF, or NT-3, will be shown to be safe or effective to treat any human condition or be approved for marketing by any regulatory agency. The delay or failure of current or future studies to demonstrate the safety or efficacy of its product candidates to treat human conditions or to be approved for marketing could have a material adverse impact on Regeneron.

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

From inception on January 8, 1988 through September 30, 2000, Regeneron had a cumulative loss of \$213.8 million. In the absence of revenues from commercial product sales or other sources (the amount, timing, nature, or source of which cannot be predicted), Regeneron's losses will continue as it conducts its research and development activities. The Company's activities may expand over time and may require additional resources, and the Company's operating losses may be substantial over at least the next several years. Regeneron's losses may fluctuate from quarter to quarter and will depend, among other factors, on the timing of certain expenses and on the progress of its research and development efforts.

#### Results of Operations

Three months ended September 30, 2000 and 1999. The Company's total revenue increased to \$17.4 million for the third quarter of 2000 from \$12.5 million for the same period in 1999. The increase in the third quarter was due primarily to the receipt of two non-recurring research progress payments totaling \$3.5 million from Procter & Gamble related to its long-term collaboration agreement with the Company. Contract research and development revenue increased to \$8.8 million for the third quarter of 2000 from \$8.6 million for the same period in 1999, as revenue from Amgen-Regeneron Partners increased to \$1.7 million in the third quarter of 2000 from \$0.8 million for the same period in 1999 due to increased clinical trial activity on BDNF and NT-3. This increase was partly offset by lower revenue from Procter & Gamble primarily because payments related to AXOKINE research stopped in the third quarter of 1999 when Procter & Gamble returned the product rights to AXOKINE to the Company. Contract manufacturing revenue, related primarily to a long-term agreement with Merck & Co.,

Inc. (Merck) to manufacture a vaccine intermediate, was \$2.6 million in the third quarter of 2000 and \$2.7 million for the same period in 1999. In the third quarter of 1999, Merck revenue was primarily compensation for services rendered related to preparing for commercial production, which began in the fourth quarter of 1999. In the third quarter of 2000, Merck revenue primarily consisted of payments related to commercial production. Investment income increased to \$2.5 million in the third quarter of 2000 from \$1.2 million for the same period in 1999 due to interest earned on the proceeds of the Company's public offering, which was completed on April 4, 2000, and the Company's sale of Common Stock to Procter & Gamble, which was completed on August 3, 2000.

The Company's total operating expenses increased to \$20.6 million in the third quarter of 2000 from \$17.5 million for the same period in 1999. Research and development expenses increased to \$14.1 million in the third quarter of 2000 from \$12.9 million for the same period in 1999, primarily as a result of higher staffing and increased activity in the Company's preclinical and clinical research programs. The loss in Amgen-Regeneron Partners increased to \$1.1 million in the third quarter of 2000 from \$1.0 million for the same period in 1999 due to the partnership's increased clinical trial activity on BDNF and NT-3. Research and development expenses (including loss in Amgen-Regeneron Partners) were approximately 74% of total operating expenses in the third quarter of 2000, compared to 79% for the same period in 1999.

General and administrative expenses increased to \$1.7 million in the third quarter of 2000 from \$1.6 million for the same period of 1999, due primarily to higher administrative staffing and related occupancy costs. Depreciation and amortization expense increased to \$1.2 million in the third quarter of 2000 from \$0.9 million in the third quarter of 1999, as a result of improvements to, and purchases of equipment for, the Company's facilities in Tarrytown, New York, and Rensselaer, New York. Contract manufacturing expenses, related primarily to the long-term Merck agreement to manufacture a vaccine intermediate at the Company's Rensselaer facility, increased to \$2.5 million in the third quarter of 2000 from \$1.0 million for the same period in 1999. In the third quarter of 1999, Merck expenses related to preparing for commercial production of the vaccine intermediate, which began in the fourth quarter of 1999. In the third quarter of 2000, Merck expenses related primarily to the costs associated with the manufacture of vaccine intermediate produced and shipped. Interest expense was \$0.1 million for the third quarter of both 2000 and 1999.

The Company's net loss for the third quarter of 2000 was \$3.2 million, or \$0.09 per share (basic and diluted), compared to a net loss of \$4.9 million, or \$0.16 per share (basic and diluted), for the same period in 1999.

Nine months ended September 30, 2000 and 1999. The Company's total revenue increased to \$45.8 million for the nine months ended September 30, 2000 from \$26.6 million for the same period in 1999. Contract research and development revenue increased to \$27.0 million for the nine months ended September 30, 2000 from \$15.3 million for the same period in 1999. Contract research and development revenue from Procter & Gamble increased to \$21.5 million for the first nine months of 2000 from \$13.5

million for the same period in 1999 as increased revenue under the companies' collaboration agreement more than offset the termination of Procter & Gamble payments related to AXOKINE research in the third quarter of 1999 after Procter & Gamble returned the product rights to AXOKINE to the Company. Revenue from Amgen-Regeneron Partners increased to \$5.0 million for the nine months ended September 30, 2000 from \$1.6 million for the same period in 1999 due to increased clinical trial activity on BDNF and NT-3. In the first nine months of 2000, research progress payments consisted of two non-recurring payments totaling \$3.5 million from Procter & Gamble related to its long-term collaboration agreement with the Company and a payment of \$3.0 million (reduced by \$0.3 million of Japanese withholding tax) from Sumitomo Pharmaceuticals related to the development of BDNF in Japan. Contract manufacturing revenue, related primarily to the Merck agreement, decreased to \$6.6 million for the nine months ended September 30, 2000, compared to \$7.3 million for the same period in 1999. In the first nine months of 1999, Merck revenue primarily was compensation for services rendered related to preparing for commercial production of the vaccine intermediate, which began in the fourth quarter of 1999. In the first nine months of 2000, Merck revenue primarily consisted of payments related to commercial production of the vaccine intermediate. Investment income for the nine months ended September 30, 2000 increased to \$6.0 million from \$4.0 million for the same period in 1999 due to interest earned on the proceeds of the Company's public offering, which was completed on April 4, 2000, and the Company's sale of Common Stock to Procter & Gamble, which was completed on August 3, 2000.

The Company's total operating expenses increased to \$59.3 million for the nine months ended September 30, 2000 from \$48.3 million for the same period in 1999. Research and development expenses increased to \$40.5 million in the first nine months of 2000 from \$35.0 million for the same period in 1999, primarily as a result of higher staffing and increased activity in the Company's preclinical and clinical research programs. The loss in Amgen-Regeneron Partners increased to \$3.5 million in the first nine months of 2000 from \$2.5 million for the same period in 1999 due to the partnership's increased clinical trial activity on BDNF and NT-3. Research and development expenses (including loss in Amgen-Regeneron Partners) were approximately 74% of total operating expenses in the first nine months of 2000, compared to 78% for the same period in 1999.

General and administrative expenses increased to \$5.2 million for the nine months ended September 30, 2000 from \$4.7 million for the same period in 1999 due primarily to higher administrative staffing and related occupancy costs. Depreciation and amortization expense increased to \$3.1 million for the nine months ended September 30, 2000 from \$2.5 million for the same period in 1999 primarily as a result of improvements made to the Company's leased facilities in Tarrytown as well as purchases of new research equipment. Contract manufacturing expenses increased to \$6.8 million for the first nine months of 2000 from \$3.5 million in the same period of 1999, due primarily to costs associated with initiating commercial production at the Company's Rensselaer

facility of both a vaccine intermediate for Merck and clinical supplies of BDNF for Sumitomo Pharmaceuticals. Interest expense was \$0.2 million for both the first nine months of 2000 and 1999.

The Company's net loss for the nine months ended September 30, 2000 was \$13.5 million, or \$0.39 per share (basic and diluted), compared to a net loss of \$21.7 million, or \$0.69 per share (basic and diluted), for the same period in 1999.

#### Liquidity and Capital Resources

Since its inception in 1988, the Company has financed its operations primarily through private placements and public offerings of its equity securities, revenue earned under the agreements between the Company and Amgen, Sumitomo Chemical Company, Ltd., Sumitomo Pharmaceuticals, Merck, and Procter & Gamble, and investment income.

In May 1997, Regeneron and Procter & Gamble entered into a long-term collaboration agreement. Procter & Gamble agreed over the first five years of the collaboration to purchase up to \$60.0 million in Regeneron equity (of which \$42.9 million was purchased in June 1997 and \$17.1 million was purchased in August 2000) and provide funding in support of Regeneron's research efforts related to the collaboration (of which \$38.0 million had been received through September 30, 2000). In August 2000, Procter & Gamble made two non-recurring research progress payments to Regeneron totaling \$3.5 million. In addition, in August 2000, Procter & Gamble and Regeneron agreed through a binding memorandum of understanding to enter into a new collaboration agreement, replacing the companies' 1997 agreement. The new agreement will extend Procter & Gamble's obligation to fund Regeneron's research under the new collaboration agreement through December 2005, with no further research obligations by either party thereafter, and focus the companies' collaborative research on therapeutic areas that are of particular interest to Procter & Gamble, including muscle atrophy and muscle diseases, fibrotic diseases, and certain G-protein coupled receptors. Any drugs that result from the collaboration will continue to be jointly developed and marketed worldwide, with the companies equally sharing development costs and profits. Under the original P&G Agreement, research support from Procter & Gamble would have been \$6.8 million per quarter (before adjustments for future inflation) for the period July 2000 through June 2002. Under the new agreement, beginning in the first quarter of 2001, research support from Procter & Gamble will be \$2.5 million per quarter (before adjustments for future inflation) through December 2005, and total funding from July 2000 through December 2005 will be approximately \$64 million.

In connection with Regeneron's agreement to collaborate with Sumitomo Pharmaceuticals in the research and development of BDNF in Japan, Sumitomo Pharmaceuticals paid the Company \$25.0 million through December 1997. The Company also received research progress payments from Sumitomo Pharmaceuticals of \$5.0 million (reduced by \$0.5 million of Japanese withholding tax) in August 1998 and \$3.0 million (reduced by \$0.3 million of Japanese withholding tax) in April 2000. In

addition, Sumitomo Pharmaceuticals has paid the Company \$27.7 million through September 30, 2000 in connection with supplying BDNF for preclinical and clinical use. Regeneron did not supply any BDNF to Sumitomo Pharmaceuticals in 1999. During the fourth quarter of 1999, Regeneron commenced production of BDNF and began capitalizing manufacturing costs into inventory. The Company expects to resume supplying BDNF to Sumitomo Pharmaceuticals for clinical use in late 2000 or 2001.

The Company's activities relating to BDNF and NT-3, as agreed upon by Amgen and Regeneron, are being compensated by Amgen-Regeneron Partners for services rendered, and the Company recognizes such amounts 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 \$54.7 million to Amgen-Regeneron Partners from the partnership's inception in June 1993 through September 30, 2000. These contributions could increase or decrease, depending upon (among other things) the nature and cost of BDNF and NT-3 studies that Amgen-Regeneron Partners may conduct and the outcomes of those studies.

From its inception in January 1988 through September 30, 2000, the Company invested approximately \$72.3 million in property, plant, and equipment. This includes \$18.5 million to acquire and renovate the Rensselaer facility and an additional \$14.1 million to complete construction at the facility pursuant to the Merck manufacturing agreement. In connection with the purchase and initial renovation of the Rensselaer facility, the Company obtained financing of \$2.0 million from the New York State Urban Development Corporation, of which \$1.6 million is outstanding. Under the terms of this UDC financing, the Company is not permitted to declare or pay dividends on its equity securities.

The Company expects that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries. On September 22, 2000, Immunex Corporation filed a request with the European Patent Office seeking the declaration of an Opposition regarding the scope of Regeneron's European patent relating to Cytokine Traps. Although the Company plans to defend the patent diligently, Regeneron cannot predict whether the scope of the patent will be affected in the future should an Opposition be declared. The Company also is currently involved in interference proceedings in the U.S. Patent and Trademark Office between Regeneron's patent applications and patent relating to CNTF issued to Synergen, Inc. Amgen acquired all outstanding shares of Synergen in 1994. To help expedite these interference proceedings, on

October 31, 2000, Amgen and Regeneron entered into an agreement whereby Regeneron acquired Amgen's patents and patent applications relating to CNTF and related molecules for \$1.0 million. Regeneron then granted back to Amgen exclusive rights under these patents and patent applications solely for human ophthalmic uses. In addition, Regeneron entered into a covenant not to sue Amgen under Regeneron's patents and patent applications relating to CNTF and related molecules solely for human ophthalmic uses.

As of September 30, 2000, the Company had no established banking arrangements through which it could obtain short-term financing or a line of credit. Additional funds may be raised through, among other things, the issuance of additional securities, other financing arrangements, and future collaboration agreements. No assurance can be given that additional financing will be available or, if available, that it will be available on acceptable terms. On April 4, 2000, Regeneron completed a public offering of 2.6 million shares of Common Stock at a price of \$29.75 per share for proceeds to the Company, after commissions and expenses, of \$72.9 million. On August 3, 2000, Regeneron sold 573,630 shares of Common Stock to Procter & Gamble at a price of \$29.75 per share for total proceeds to the Company of \$17.1 million. The sale of stock was made pursuant to a 1997 securities purchase agreement between Regeneron and Procter & Gamble.

At September 30, 2000, the Company had \$158.5 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 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. Regeneron believes that its existing capital resources will enable it to meet operating needs for the next two years. However, this is a forward-looking statement based on the Company's current operating plan and 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. Regeneron's cash requirements may vary materially from those now planned depending on a number of factors, including the status of competitive products, the success of Regeneron's research and development activities, the status of patents and other intellectual property rights developments, the delay or failure of a clinical trial of any of Regeneron's potential drug candidates, and the continuation, extent, and success of any collaborative research programs (including those with Amgen and Procter & Gamble). As stated previously, Regeneron has no committed external sources of capital to obtain short-term financing or a line of credit. Regeneron may seek additional financing, such as through future offerings of equity or debt securities or agreements with corporate partners and collaborators with respect to the development of potential drug candidates, to fund operations, but no assurance can be given that the Company will be able to obtain additional funds.

## Impact of the Adoption of Recently Issued Accounting Standards

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

In the period of adoption, companies will be required to report the cumulative effect of this change in accounting principle as a separate component in net income (or loss). Regeneron is required to adopt SAB 101 during the quarter ended December 31, 2000, and is currently evaluating how to apply SAB 101 and the impact that it will have on the Company's financial statements. Although the effects of SAB 101 cannot be fully determined at this time, the Company estimates that, if SAB 101 had been adopted as of September 30, 2000, the cumulative charge to earnings, and corresponding increase in deferred revenue which will be recognized in future periods, would have been less than \$6 million.

In March 2000, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation ("FIN 44"). FIN 44 interprets the provisions of APB Opinion No. 25 that provide guidance on how companies should account for stock compensation granted to employees and is effective for periods beginning on and after July 1, 2000. Management does not believe that the adoption of FIN 44 will have a material effect on the Company's financial position and results of operations.

## Factors That May Affect Future Operating Results

Regeneron cautions stockholders and potential investors that the following important factors, among others, in some cases have affected, and in the future could affect, Regeneron's actual results and could cause Regeneron's actual results to differ materially from those expressed in any forward-looking statements made by, or on behalf of, Regeneron. The statements under this caption are intended to serve as cautionary statements within the meaning of the Private Securities Litigation Reform Act of 1995. The following information is not intended to limit in any way the characterization of other statements or information under other captions as cautionary statements for such purpose:

- o Delay, difficulty, or failure of the Company's research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by the Company or others.
- o Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, those with Procter & Gamble and Amgen) and the resulting loss of research or other funding could have a material adverse effect on the Company and its operations. A change of control of one or

more of the Company's material collaborators or licensees could also have a material adverse effect on the Company.

- o Delay, difficulty, or failure of a clinical trial of any of the Company's product candidates. A clinical trial can fail or be delayed as a result of many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (side effects) caused by or connected with exposure to the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol.
- o In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by Regeneron's drug candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross-react with the patient's own proteins, resulting in an "auto-immune type" disease. Whether antibodies will be created can often not be predicted from preclinical experiments and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date -- in some cases even after pivotal clinical trials have been successfully completed. Patients who have been treated with AXOKINE, BDNF, and NT-3 have developed antibodies, though we have no information that indicates that these antibodies are neutralizing antibodies.
- o Delay, difficulty, or failure in obtaining regulatory approval (including approval of its facilities for production) for the Company's products, including delays or difficulties in development because of insufficient proof of safety or efficacy.
- o Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.
- o Competitive or market factors that may cause use of the Company's products to be limited or otherwise fail to achieve broad acceptance.
- o The ability to obtain, maintain, and prosecute intellectual property rights and the cost of acquiring in-process technology and other intellectual property rights, either by license, collaboration, or purchase of another entity.
- o The inability to raise sufficient funds to complete the development of any of our product candidates or to continue operations. As a result, Regeneron may face delay, reduction or cancellation of research and development programs or preclinical or clinical trials.

- o Difficulties or high costs of obtaining adequate financing to meet the Company's obligations under its collaboration and licensing agreements or to fund 50 percent of the cost of developing product candidates in order to retain 50 percent of the commercialization rights.
- o Amount and rate of growth of Regeneron's general and administrative expenses, and the impact of unusual charges resulting from Regeneron's ongoing evaluation of its business strategies and organizational structure.
- o Failure of corporate partners to develop or commercialize successfully the Company's products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between Regeneron and its corporate partners.
- o Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology product in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.
- o Difficulties in obtaining key raw materials and supplies for the manufacture of the Company's product candidates.
- o The costs and other effects of legal and administrative cases and proceedings (whether civil, such as product- or employment-related, or environmental, or criminal); settlements and investigations; developments or assertions by or against Regeneron relating to intellectual property rights and licenses; the issuance and use of patents and proprietary technology by Regeneron and its competitors, including the possible negative effect on the Company's ability to develop, manufacture, and sell its products in circumstances where it is unable to obtain licenses to patents which may be required for such products.
- o Underutilization of the Company's existing or new manufacturing facilities or of any facility expansions, resulting in inefficiencies and higher costs; start-up costs, inefficiencies, delays, and increased depreciation costs in connection with the start of production in new plants and expansions.
- o Health care reform, including reductions or changes in reimbursement available for prescription medications or other reforms.
- o Difficulties in attracting and retaining key personnel.

As Regeneron's scientific efforts lead to potentially promising new directions, both outside of recombinant protein therapies and into conditions or diseases outside of Regeneron's current areas of experience and expertise, the Company will require

additional internal expertise or external collaborations in areas in which it currently does not have substantial resources and personnel.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

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

PART II. OTHER INFORMATION

Item 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 September 30, 2000.

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: November 14, 2000

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

9-MOS	DEC-31-2000		
	JAN-01-2000		
	SEP-30-2000		
		49,642	
		108,857	
		9,851	
		0	
		8,181	
	137,002		72,281
		34,622	
		216,319	
	12,742		0
	0		0
		0	34
		190,938	
216,319			0
	45,827		0
			0
	59,076		
	0		
	0		
	227		
	(13,476)		
		0	
	(13,476)		
		0	
		0	
			0
	(13,476)		
		(0.39)	
		(0.39)	