Table of Contents

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, 2001

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 October 31, 2001:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,570,789
Common Stock, $0.001 par value	41,163,133

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION
- ITEM 1. FINANCIAL STATEMENTS
  - CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2001 AND DECEMBER 31, 2000 (Unaudited)
  - CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
  - CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the nine months ended September 30, 2001
  - CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)
  - Notes to Condensed Financial Statements
- Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Item 3. Quantitative and Qualitative Disclosure About Market Risk.

PART II. OTHER INFORMATION
- Item 6. Exhibits and Reports on Form 8-K

SIGNATURE

REGENERON PHARMACEUTICALS, INC.
Table of Contents
September 30, 2001

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at September 30, 2001 and December 31, 2000	3
	Condensed statements of operations (unaudited) for the three months and nine months ended September 30, 2001 and 2000	4
	Condensed statement of stockholders' equity (unaudited) for the nine months ended September 30, 2001	5
	Condensed statements of cash flows (unaudited) for the nine months ended September 30, 2001 and 2000	6
	Notes to condensed financial statements	7-15
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	16-27
Item 3	Quantitative & Qualitative Disclosure About Market Risk	28
PART II	**OTHER INFORMATION**	
Item 6	Exhibits and Reports on Form 8-K	29
SIGNATURE PAGE		30

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2001 AND DECEMBER 31, 2000 (Unaudited)
(In thousands, except share data)

ASSETS	September 30, 2001	December 31, 2000
Current assets		
Cash and cash equivalents	$ 99,974	$ 30,978
Marketable securities	140,735	86,634
Receivable due from The Procter & Gamble Company	2,500	6,907
Receivable due from Merck & Co., Inc.	334	1,447
Receivable due from Amgen-Regeneron Partners	713	1,604
Receivable due from Sumitomo Pharmaceuticals Co., Ltd.		3,877
Prepaid expenses and other current assets	5,415	780
Inventory	3,056	1,915
Total current assets	252,727	134,142
Marketable securities	27,319	36,758
Investment in Amgen-Regeneron Partners	867	267
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	37,418	36,934
Other assets	282	173
Total assets	$ 318,613	$ 208,274
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 10,120	$ 9,446
Deferred revenue, current portion	3,772	3,728
Capital lease obligations, current portion	456	545
Note payable, current portion	67	67
Total current liabilities	14,415	13,786
Deferred revenue	7,394	9,995
Capital lease obligations	230	603
Note payable	1,416	1,466
Other liabilities	287	294
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; 2,570,789 shares issued and outstanding in 2001		
2,612,845 shares issued and outstanding in 2000	3	3
Common Stock, $.001 par value; 60,000,000 shares authorized; 41,160,798 shares issued and outstanding in 2001		
34,197,104 shares issued and outstanding in 2000	41	34
Additional paid-in capital	565,435	406,391
Unearned compensation	(999)	(1,314)
Accumulated deficit	(271,320)	(223,518)
Accumulated other comprehensive income	1,711	534
Total stockholders' equity	294,871	182,130
Total liabilities and stockholders' equity	$ 318,613	$ 208,274

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,	
	2001	2000	2001	2000
Revenues				
Contract research and development	$ 2,819	$ 8,876	$ 9,351	$ 27,322
Research progress payments		3,500		6,200
Contract manufacturing	2,661	2,623	8,221	6,617
	5,480	14,999	17,572	40,139
Expenses				
Research and development	25,039	15,207	61,440	43,508
Contract manufacturing	1,274	2,512	5,347	6,828
General and administrative	2,461	1,769	6,875	5,290
	28,774	19,488	73,662	55,626
Loss from operations	(23,294)	(4,489)	(56,090)	(15,487)
Other income, net				
Investment income	3,162	2,530	9,474	5,967
Earnings from (loss in) Amgen-Regeneron Partners	241	(1,099)	(1,056)	(3,450)
Interest expense	(40)	(60)	(130)	(227)
	3,363	1,371	8,288	2,290
Net loss before cumulative effect of a change in accounting principle	(19,931)	(3,118)	(47,802)	(13,197)
Cumulative effect of adopting Staff Accounting Bulletin 101 (“SAB 101”)				(1,563)
Net loss	($19,931)	($3,118)	($47,802)	($14,760)
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	($0.46)	($0.09)	($1.15)	($0.38)
Cumulative effect of adopting SAB 101				(0.05)
Net loss	($0.46)	($0.09)	($1.15)	($0.43)

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, 2001
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation
	Shares	Amount	Shares	Amount		
Balance, December 31, 2000	2,613	$ 3	34,197	$34	$406,391	($1,314)
Issuance of Common Stock in a public offering at $25.00 per share			6,630	7	165,743	
Cost associated with issuance of equity securities					(9,076)	
Issuance of Common Stock in connection with exercise of stock options			230		1,678	
Issuance of restricted Common Stock under Long-Term Incentive Plan			8		222	(222)
Issuance of Common Stock to Medtronic, Inc. in connection with a cashless exercise of warrants			37			
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			17		477	
Conversion of Class A Stock to Common Stock	(42)		42			
Amortization of unearned compensation						537
Net loss						
Change in net unrealized gain on marketable securities						
Balance, September 30, 2001	2,571	$ 3	41,161	$41	$565,435	($999)

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Loss
Balance, December 31, 2000	($223,518)	$ 534	$182,130	
Issuance of Common Stock in a public offering at $25.00 per share			165,750	
Cost associated with issuance of equity securities			(9,076)	
Issuance of Common Stock in connection with exercise of stock options			1,678	
Issuance of restricted Common Stock under Long-Term Incentive Plan				
Issuance of Common Stock to Medtronic, Inc. in connection with a cashless exercise of warrants				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			477	
Conversion of Class A Stock to Common Stock				
Amortization of unearned compensation			537	
Net loss	(47,802)		(47,802)	($47,802)
Change in net unrealized gain on marketable securities		1,177	1,177	1,177
Balance, September 30, 2001	($271,320)	$1,711	$294,871	($46,625)

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30,	
	2001	**2000**
Cash flows from operating activities		
Net loss	($47,802)	($14,760)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss in Amgen-Regeneron Partners	1,056	3,450
Depreciation and amortization	4,267	3,125
Cumulative effect of a change in accounting principle		1,563
Non-cash compensation expense	537	
Changes in assets and liabilities:		
Decrease (increase) in amounts due from The Procter & Gamble Company	4,407	(6,907)
Decrease (increase) in amounts due from Merck & Co., Inc.	1,113	(694)
Decrease (increase) in amounts due from Amgen-Regeneron Partners	891	(1,653)
Decrease (increase) in amounts due from Sumitomo Pharmaceuticals Co., Ltd.	3,877	(307)
Increase in investment in Amgen-Regeneron Partners	(1,656)	(3,637)
Increase in prepaid expenses and other assets	(4,674)	(1,254)
Increase in inventory	(304)	(2,494)
Decrease in deferred revenue	(2,557)	(2,178)
Increase in accounts payable, accrued expenses, and other liabilities	1,179	1,606
Total adjustments	8,136	(9,380)
Net cash used in operating activities	(39,666)	(24,140)
Cash flows from investing activities		
Purchases of marketable securities	(120,766)	(75,517)
Sales of marketable securities	77,211	37,904
Capital expenditures	(5,623)	(5,330)
Net cash used in investing activities	(49,178)	(42,943)
Cash flows from financing activities		
Net proceeds from the issuance of stock	158,352	94,204
Principal payments on note payable	(50)	(45)
Capital lease payments	(462)	(1,131)
Net cash provided by financing activities	157,840	93,028
Net increase in cash and cash equivalents	68,996	25,945
Cash and cash equivalents at beginning of period	30,978	23,697
Cash and cash equivalents at end of period	$ 99,974	$ 49,642

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

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

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2000 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, 2000. As discussed in Notes 2 and 13 below, the operating results for the three and nine months ended September 30, 2000 have been restated from amounts previously reported to reflect the adoption of a new accounting principle for revenue recognition and reclassification of depreciation and amortization expense, respectively.

2. Revenue Recognition and Change in Accounting Principle

During the fourth quarter of 2000, the Company changed its method of accounting for revenue recognition to conform with the guidance provided by Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"). The change in accounting method was effective January 1, 2000 and, accordingly, the previously issued interim financial statements for the quarters ended March 31, June 30, and September 30, 2000 have been restated to reflect the adoption of SAB 101 as if it had occurred on January 1, 2000. The cumulative effect of adopting SAB 101 at January 1, 2000 amounted to $1,563 of additional loss as of that date, with a corresponding increase to deferred revenue to be recognized in subsequent periods. $279 of that deferred revenue, or $93 per quarter, is included in contract research and development revenue in both the nine month period ended September 30, 2001 and 2000. The $1,563 represents a portion of a 1989 payment received from Sumitomo Chemical Company, Ltd. in consideration for a fifteen year limited right of first negotiation to license up to three of the Company's product candidates in Japan. The effect of income taxes on the cumulative effect adjustment was immaterial.

3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2001 and December 31, 2000 are $637 and $672, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2000 and December 31, 1999 are $988 and $697, respectively, of accrued capital expenditures.

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

Included in accounts payable and accrued expenses at December 31, 2000 and 1999 are $477 and $421, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2001 and 2000, the Company contributed 17,484 and 54,003 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2001 and December 31, 2000 are $2,276 and $2,346 of accrued interest income, respectively. Included in marketable securities at September 30, 2000 and December 31, 1999 are $2,214 and $1,163 of accrued interest income, respectively.

4. Inventories

Inventories consist primarily of raw materials and other direct and indirect costs associated with production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement.

Inventories as of September 30, 2001 and December 31, 2000 consist of the following:

	September 30, 2001	December 31, 2000
Raw materials	$ 385	$ 535(2)
Work-in-process	44(1)	53(3)
Finished products	2,627	1,327
	$3,056	$1,915

(1) Net of reserves of $230.
(2) Net of reserves of $255.
(3) Net of reserves of $830.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2001 and December 31, 2000 consist of the following:

	September 30, 2001	December 31, 2000
Accounts payable	$ 2,511	$2,590
Accrued payroll and related costs	3,327	2,630
Accrued clinical trial expense	3,003	2,308
Accrued expenses, other	1,279	1,918
	$10,120	$9,446

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

6. Amgen-Regeneron Partners Research Collaboration Agreement

In August 1990, the Company entered into a collaboration with Amgen Inc. ("Amgen") to develop and attempt to commercialize brain derived neurotrophic factor ("BDNF") and neurotrophin-3 ("NT-3") in the United States. Pursuant to that agreement, the Company and Amgen formed a partnership, Amgen-Regeneron Partners (the "Partnership"). The Company accounts for its investment in the Partnership in accordance with the equity method of accounting.

In January 2001, the Partnership discontinued all clinical development of BDNF for the potential treatment of amyotrophic lateral sclerosis ("ALS") following notification that BDNF did not provide a therapeutic advantage to ALS patients in clinical trials.

Selected operating statement data of the Partnership for the three and nine months ended September 30, 2001 and 2000 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Interest income	$ 37	$ 96	$ 150	$ 295
Total expenses	446[a]	(2,295)	(2,261)	(5,312)
Net income (loss)	$483	($2,199)	($2,111)	($5,017)

[a] In connection with the discontinuance of BDNF clinical development, in the third quarter of 2001, the Partnership reduced previously estimated and accrued costs to wind-down the BDNF clinical study by $773.

7. 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, 2001 and 2000, the components of comprehensive loss are:

	Nine Months Ended September 30,	
	2001	2000
Net loss	($47,802)	($14,760)
Change in net unrealized gain on marketable securities	1,177	291
Total comprehensive loss	($46,625)	($14,469)

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

8. Equity Transactions

On March 23, 2001 the Company completed a public offering in which it issued 6.5 million shares of Common Stock at a price of $25.00 per share and received proceeds, after commissions and expenses, of $153.6 million. On April 11, 2001, the Company sold an additional 130,000 shares of Common Stock pursuant to the underwriters' over-allotment option from the March 2001 public offering at a price of $25.00 per share for proceeds to the Company, after commissions and expenses, of $3.1 million.

In March 2001, Medtronic, Inc. exercised 107,400 warrants with an exercise price of $21.72 per share on a "cashless" basis and received 37,306 shares of the Company's Common Stock.

9. Stock Compensation

The Company awards shares of Restricted Stock under the Regeneron Pharmaceuticals, Inc. Long-Term Incentive Plan. Restrictions on these shares lapse with respect to 25% of the shares every six months over a two-year period. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to these awards. The amount is based on the fair market value of shares of the Company's Common Stock on the grant date of the Restricted Stock award and is expensed, on a pro rata basis, over the two year period that the restrictions lapse. For the three and nine months ended September 30, 2001, the Company recognized compensation expense related to Restricted Stock awards of $168 and $537, respectively. No stock-based compensation expense was recognized during 2000.

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

10. 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, 2001 and 2000, 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, in thousands (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2001:			
Basic and Diluted	($19,931)	43,682	($0.46)
2000:			
Basic and Diluted	($3,118)	36,134	($0.09)

	Nine Months Ended September 30,		
	Net Loss, in thousands (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2001:			
Basic and Diluted	($47,802)	41,567	($1.15)
2000:			
Basic and Diluted	($14,760)	34,344	($0.43)

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,	
	2001	2000	2001	2000
Weighted Average Number, in thousands	7,467	6,480	7,542	7,057
Weighted Average Exercise Price	$19.22	$12.31	$19.10	$11.65

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

11. Segment Reporting

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

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

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produces an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement and, in 2000, produced BDNF for Sumitomo Pharmaceuticals Co., Ltd. under a research and development agreement.

The tables below present information about reported segments for the three and nine months ended September 30, 2001 and 2000:

	Three Months Ended September 30, 2001			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$2,819	$ 2,661	—	$5,480
Earnings from Amgen-Regeneron Partners	241	—	—	241
Depreciation and amortization	1,519	—(2)	—	1,519
Interest expense	30	10	—	40
Net (loss) income	(24,470)	1,377	$3,162(1)	(19,931)
Capital expenditures	1,597	—	—	1,597

	Three Months Ended September 30, 2000			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$12,376	$2,623	—	$ 14,999
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	(5,741)	93	$2,530(1)	(3,118)
Capital expenditures	1,731	2	—	1,733

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

	Nine Months Ended September 30, 2001			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$9,351	$8,221	—	$17,572
Loss in Amgen-Regeneron Partners	(1,056)	—	—	(1,056)
Depreciation and amortization	4,267	—(2)	—	4,267
Interest expense	94	36	—	130
Net (loss) income	(60,114)	2,838	$9,474(1)	47,802
Capital expenditures	5,563	25	—	5,588
Total assets	35,890	8,998	273,725(3)	318,613

	Nine Months Ended September 30, 2000			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$33,522	$6,617	—	$40,139
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	(20,442)	(285)	$5,967(1)	(14,760)
Capital expenditures	5,555	65	—	5,620
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. Legal Matters

In September 2000, Immunex Corporation filed a request with the European Patent Office seeking the declaration of an Opposition regarding the scope of the Company's European patent relating to Cytokine Traps. This is a legal challenge to the validity and scope of the Company's patent. Although the Company plans to defend the patent diligently, the scope of the patent may be adversely affected following the outcome of the Opposition. In addition to this patent challenge, the Company, from time to time, has been subject to legal claims arising in connection with its business. While the ultimate results of the patent challenge and legal claims cannot be predicted with certainty, at September 30, 2001 there were no asserted claims against the Company which, in the opinion of management, if adversely decided would have a material adverse effect on the Company's financial position, results of operations, and cash flows.

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

13. Reclassifications

Certain reclassifications have been made to the financial statements for the three and nine months ended September 30, 2000 to conform with the current period's presentation.

Effective in 2001, the Company's financial statement presentation of depreciation and amortization in the Statements of Operations has been changed to allocate depreciation and amortization between research and development expense and general and administrative expense. Depreciation and amortization related to contract manufacturing expense was already included in contract manufacturing expense in 2000. The effect of this reclassification for the three and nine months ended September 30, 2000 and for the year ended December 31, 2000 is presented in the following table.

	Third Quarter Ended September 30, 2000 (Unaudited)		Nine Months Ended September 30, 2000 (Unaudited)	
	As Previously Reported	As Reclassified	As Previously Reported	As Reclassified
Expenses:				
Research and development	$14,085	$15,207	$40,470	$43,508
General and administrative	1,737	1,769	5,203	5,290
Depreciation and amortization	1,154		3,125	
Contract manufacturing	2,512	2,512	6,828	6,828
Total	$19,488	$19,488	$55,626	$55,626

	Year Ended December 31, 2000 (Unaudited)	
	As Previously Reported	As Reclassified
Expenses:		
Research and development	$56,256	$60,559
General and administrative	8,309	8,427
Depreciation and amortization	4,421	
Contract manufacturing	15,566	15,566
Total	$84,552	$84,552

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

14. Future Impact of Recently Issued Accounting Standards

The Financial Accounting Standards Board has recently issued Statement of Financial Accounting Standards ("SFAS") No. 141, *Business Combinations*, SFAS No. 142, *Goodwill and Other Intangible Assets*, SFAS No. 143, *Accounting for Obligations Associated with the Retirement of Long-Lived Assets*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which the Company will be required to adopt in future periods. Management believes that the future adoption of these accounting standards will not have a material impact on the Company's financial statements.

15. Subsequent Events

a. Extinguishment of Note Payable

In 1994, the Company borrowed $2.0 million from the New York State Urban Development Corporation, of which approximately $1.5 million remained outstanding at September 30, 2001. The terms of the note provided for monthly payments of principal and interest through December 2014. On October 11, 2001, the remaining principal balance on this note was paid in full.

b. Issuance of Convertible Senior Subordinated Notes

On October 17, 2001, the Company issued $200 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company, after deducting the initial purchasers' discount and before out-of-pocket expenses, of $193.4 million. The Notes bear interest at 5.5% per annum, payable semi-annually, and mature on October 17, 2008. The Notes are convertible into shares of the Company's Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. Regeneron may redeem the Notes, in whole or in part, at any time before October 17, 2004 if the closing price of the Company's Common Stock has exceeded 150% of the conversion price then in effect for a specified period of time ("Early Redemption"). Upon any such Early Redemption, the Company is required to pay interest that would have been due up through October 17, 2004. Regeneron may also redeem some or all of the Notes at any time on or after October 17, 2004 if the closing price of the Company's Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time. The Company pledged $31.6 million of U.S. government securities which will be sufficient upon receipt of scheduled principal and interest payments to provide for the payment in full of the first six scheduled interest payments on the Notes when due.

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

General

Overview. *The discussion below contains forward-looking statements that involve risks and uncertainties relating to the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Factors That May Affect Future Operating Results" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.*

Regeneron Pharmaceuticals, Inc., which may be referred to as "we", "us", or "our", is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic drugs for the treatment of serious medical conditions. Our product pipeline includes product candidates for the treatment of obesity, rheumatoid arthritis and other inflammatory conditions, cancer and related disorders, allergies, asthma, and other diseases and disorders. Since inception, we have not generated sales or any profits from the commercialization of any of our product candidates.

Our core business strategy is to combine our strong foundation in science and technology with state-of-the-art manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse and growing pipeline of product candidates that have the potential to address a variety of unmet medical needs. Our ability to develop product candidates results from the application of our technology platforms. In contrast to basic genomics approaches which attempt to identify every gene in a cell or genome, our technology platforms are designed to discover specific genes of therapeutic interest for a particular disease or cell type. We will continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

A key aspect of our strategy is to retain significant ownership and commercialization rights to our pipeline. Below is a summary of our leading clinical programs, as well as several product candidates that are expected to enter clinical trials over the next two years. We retain sole ownership and marketing rights for each of these programs and currently are developing them independent of any corporate partners.

- **AXOKINE®:** Acts on the brain region regulating food intake and energy expenditure and is being developed for the treatment of obesity. In November 2000, we announced the preliminary results of a twelve-week Phase II dose-ranging trial of AXOKINE in 170 severely obese patients. In the trial, AXOKINE was generally well tolerated and was not associated with any reported serious adverse effects. Patients treated with AXOKINE showed medically meaningful and statistically significant weight loss compared to those receiving placebo. In September 2001, we reported that patients who completed 36 weeks of follow-up after cessation of treatment, on average, maintained the weight loss observed in the twelve-week treatment period. We initiated a Phase III clinical program testing AXOKINE in overweight and obese patients in July 2001. The initial study will enroll approximately 2,000 patients in over 60 sites across the United States.

- **PEGYLATED AXOKINE:** Chemically modified version of AXOKINE that is being developed as a more potent, longer-acting form of the protein. Pegylated AXOKINE currently is in late-stage preclinical development and we anticipate initiating a Phase I clinical trial in the first half of 2002.

- **INTERLEUKIN-1 CYTOKINE TRAP (IL-1 Trap):** Protein-based antagonist for the interleukin-1 (called IL-1) cytokine. IL-1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In December 2000, we initiated a Phase I study to assess the safety and tolerability of the IL-1 Trap in patients with rheumatoid arthritis. We expect the study to be completed in the fourth quarter of 2001 and to begin a Phase II study in the first half of 2002.

- **INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/IL-13 Trap):** Protein-based antagonist for the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines which are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. We expect to initiate a Phase I clinical trial of a dual IL-4/IL-13 Trap for asthma/allergy related conditions in the first half of 2002.

- **VEGF TRAP:** Protein-based antagonist to Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF). VEGF is required for the growth of blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leak. The VEGF Trap is expected to enter Phase I clinical trials in the first quarter of 2002.

- **ANGIOPOIETINS:** A new family of growth factors that act specifically on the endothelium cells that line blood vessels. Angiopoietins may be useful for growing blood vessels in diseased hearts and other tissues with decreased blood flow and for repairing blood vessel leaks that cause swelling and edema in many different diseases such as stroke, diabetic retinopathy, and inflammatory diseases. Selected Angiopoietins, including engineered forms of these growth factors, are in preclinical development.

In addition to the above programs which we are conducting independent of any corporate partners, we have formed collaborations to advance other research and development efforts. We are conducting research with The Procter & Gamble Company in muscle diseases and other fields. We are also collaborating with Medarex, Inc. to discover, develop, and commercialize certain human antibodies as therapeutics. In partnership with Amgen Inc., we have development rights to Neurotrophin-3, or NT-3, a clinical compound for the treatment of constipating conditions. In all of these research collaborations, we retain 50% of the commercialization rights.

Discussion of Third Quarter 2001 Activities

In November 2000, we announced the preliminary results of a Phase II clinical trial, which tested the safety and efficacy of AXOKINE in severely obese patients. The Phase II trial was a randomized, double-blind, placebo-controlled, out-patient study conducted with 170 patients at seven sites in the United States. The trial established an optimal daily dose of AXOKINE of 1.0 mcg/kg. Patients who received the optimal dose over the twelve-week treatment period averaged 10 pounds more weight loss than patients on placebo. Moreover, 46% of the patients in the optimal dose group lost at least 10 pounds, compared with just 5% of the patients who received placebo. No serious adverse events associated with the drug were reported during the trial and the drug was generally well tolerated. In September 2001, we reported that patients who completed 36 weeks of follow-up after cessation of treatment, on average, maintained the weight loss observed in the twelve-week treatment period.

In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese patients. The initial pivotal trial will enroll approximately 2,000 patients at over 60 study sites across the United States in a double-blind, randomized, placebo-controlled study. This trial will have a twelve-month treatment period, in which patients will receive daily subcutaneous self-injections of placebo or AXOKINE at a dose of 1.0 microgram (mcg) per kilogram (kg) of body weight. The treatment period will be followed by a twelve-month open-label safety extension phase, during which all patients will receive AXOKINE. Endpoints of the study are based on changes in body weight versus baseline during the treatment period. As part of the overall Phase III program, Regeneron will conduct additional confirmatory and ancillary studies of AXOKINE in obese and obese diabetic patients. These studies will vary in duration and size and are planned to be completed within the same time frame as the initial pivotal study described above. The Phase III program is expected to enroll over 4,000 subjects in total.

Amgen-Regeneron Partners, the partnership equally owned by Amgen Inc. and us, has the development rights to NT-3 in the United States. In 2000, we, on behalf of Amgen-Regeneron Partners initiated Phase II studies of NT-3 in patients with functional constipation and spinal cord injury patients with bowel dysfunction. We are currently evaluating preliminary data from these studies, and based in part on this data Amgen-Regeneron Partners will determine whether and how to proceed with the development of NT-3.

Regeneron's Board of Directors approved amendments to our insider trading policy permitting officers, directors and employees to enter into written trading plans complying with Rule 10b5-1 adopted by the Securities and Exchange Commission. Each Rule 10b5-1 trading plan may provide for purchases and sales of our securities subject to certain pre-specified conditions.

A minority of all research and development programs ultimately results in commercially successful pharmaceutical drugs; it is not possible to predict whether any program will succeed until it actually produces a medicine that is commercially marketed for a significant period of time. In addition, in each of the areas of our independent and collaborative activities, other companies and entities are actively pursuing competitive paths toward similar objectives. The results of Regeneron's and its collaborators' past activities in connection with the research and development of AXOKINE, Cytokine Traps, Angiopoietins, cancer, abnormal bone growth, muscle atrophy, small molecules, NT-3, and other programs or areas of research or development do not necessarily predict the results or success of current or future activities including, but not limited to, any additional preclinical or clinical studies. We cannot predict whether, when, or under what conditions any of our research or product candidates, including without limitation AXOKINE, IL-1 Trap, 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. We discuss the risks associated with pharmaceutical drug development in the section of this report titled "Factors That May Affect Future Operating Results."

We have not received revenue from the commercialization of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing our research and development efforts and obtaining regulatory approval from the FDA or regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies noncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2001, we had a cumulative loss of $271.3 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Our activities may expand over time and may require additional resources and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the timing of certain expenses and on the progress of our research and development efforts.

Results of Operations

Three months ended September 30, 2001 and 2000. Our total revenue decreased to $5.5 million for the third quarter of 2001 from $15.0 million for the same period in 2000. Contract research and development revenue decreased to $2.8 million in the third quarter of 2001 from $8.9 million for the same period in 2000. Under our long-term collaboration agreement with Procter & Gamble, research payments decreased effective in the first quarter of 2001 to $2.5 million per quarter versus $6.8 million for the same period of 2000. In addition, revenue from Amgen-Regeneron Partners decreased to $0.2 million for the third quarter of 2001 from $1.7 million for the same period in 2000 due to the cessation of clinical trial activity on brain derived neurotrophic factor, or BDNF, in January 2001 and the substantial completion of our Phase II studies of NT-3. In the third quarter of 2000, we received two non-recurring research progress payments totaling $3.5 million from Procter & Gamble related to our long-term collaboration agreement. Contract manufacturing revenue, related primarily to a long-term agreement with Merck & Co., Inc. (Merck) to manufacture a vaccine intermediate, was $2.7 million and $2.6 million for the third quarters of 2001 and 2000, respectively.

Our total operating expenses increased to $28.8 million in the third quarter of 2001 from $19.5 million for the same period in 2000. Research and development expenses increased to $25.0 million in the third quarter of 2001 from $15.2 million for the same period in 2000, primarily as a result of higher staffing and increased activity in our preclinical and clinical development programs. For example, in July 2001, we initiated a Phase III clinical program of AXOKINE for the treatment of obesity. Research and development expenses were 87% of total operating expenses in the third quarter of 2001, compared to 78% for the same period in 2000. Contract manufacturing expenses decreased to $1.3 million in the third quarter of 2001 from $2.5 million for the same period in 2000, due primarily to higher costs in 2000 associated with initiating commercial production at our Rensselaer, New York facility of both vaccine intermediate for Merck and BDNF for clinical use by Sumitomo Pharmaceuticals Co., Ltd. We stopped producing clinical supplies of BDNF for Sumitomo Pharmaceuticals at the end of 2000. General and administrative expenses increased to $2.5 million in the third quarter of 2001 from $1.8 million for the same period of 2000, due primarily to higher administrative staffing and related occupancy costs.

Investment income increased to $3.2 million for the third quarter of 2001 from $2.5 million for the same period in 2000 due primarily to interest earned on the proceeds of our public offering in March 2001. We earned $0.2 million from Amgen-Regeneron Partners for the third quarter of 2001 compared to a loss of $1.1 million for the same period in 2000. The partnership discontinued clinical trial activity on BDNF in January 2001 and has substantially completed Phase II studies of NT-3. The partnership’s third quarter 2001 net income is attributable to a $0.8 million reduction of previously estimated costs to wind-down the BDNF clinical study.

Our net loss for the third quarter of 2001 was $19.9 million, or $0.46 per share (basic and diluted), compared with a net loss of $3.1 million, or $0.09 per share (basic and diluted), for the same period in 2000.

Nine months ended September 30, 2001 and 2000. Our total revenue decreased to $17.6 million for the nine months ended September 30, 2001 from $40.1 million for the same period in 2000, as higher contract manufacturing revenue was more than offset by decreases in contract research and development revenue and research progress payments. Contract research and development revenue decreased to $9.4 million for the nine months ended September 30, 2001 from $27.3 million for the same period in 2000. Under our long-term collaboration agreement with Procter & Gamble, research payments decreased effective in the first quarter of 2001 to $2.5 million per quarter from $7.1 million per quarter for the first two quarters of 2000 and $6.8 million for the third quarter of 2000. In addition, revenue from Amgen-Regeneron Partners decreased to $1.3 million for the nine months ended September 30, 2001 from $5.0 million for the same period in 2000, due primarily to the cessation of clinical trial activity on BDNF in January 2001. 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 our long-term collaboration agreement 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 our long-term agreement with Merck to manufacture a vaccine intermediate, increased to $8.2 million in the first nine months of 2001 from $6.6 million for the same period in 2000, due to an increase in the revenue we received per shipment of intermediate to Merck during the first nine months of 2001.

Our total operating expenses increased to $73.7 million for the nine months ended September 30, 2001 from $55.6 million for the same period in 2000. Research and development expenses increased to $61.4 million in the first nine months of 2001 from $43.5 million for the same period in 2000, primarily as a result of higher staffing and increased activity in our preclinical and clinical development programs. Research and development expenses were 83% of total operating expenses for the first nine months of 2001, compared to 78% for the same period in 2000. Contract manufacturing expenses decreased to $5.3 million in the first nine months of 2001 from $6.8 million for the same period in 2000 due, in part, to higher costs in 2000 associated with initiating commercial production at our Rensselaer, New York facility of both vaccine intermediate for Merck and BDNF for clinical use by Sumitomo Pharmaceuticals. We stopped producing clinical supplies of BDNF for Sumitomo Pharmaceuticals at the end of 2000. General and administrative expenses increased to $6.9 million in the first nine months of 2001 from $5.3 million for the same period of 2000, due primarily to higher administrative staffing and related occupancy costs.

Investment income increased to $9.5 million for the nine months ended September 30, 2001 from $6.0 million for the same period in 2000 due to interest earned on the proceeds of our public offerings in March 2001 and April 2000 and our sale of Common Stock to Procter & Gamble in August 2000. The loss in Amgen-Regeneron Partners

decreased to $1.1 million for the first nine months of 2001 from $3.5 million for the same period in 2000 due primarily to the cessation of clinical trial activity on BDNF in January 2001.

During the fourth quarter of 2000, we changed our method of accounting for revenue recognition to conform with the guidance provided by Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, (SAB 101). The change in accounting method was effective January 1, 2000 and, as a result, we restated the previously issued interim financial statements for the nine months ended September 30, 2000 to reflect the adoption of SAB 101 as if it had occurred on January 1, 2000. The cumulative effect of adopting SAB 101 as of January 1, 2000 was to increase our net loss by $1.6 million as of that date, or $0.05 per share, with a corresponding increase to deferred revenue to be recognized in subsequent periods. The SAB 101 adjustment relates to a portion of a 1989 payment received from Sumitomo Chemical Company, Ltd. in consideration for a fifteen year limited right of first negotiation to license up to three of our product candidates in Japan. In the first nine months of both 2001 and 2000, we recognized contract research and development revenue of $0.3 million that was included in the cumulative effect adjustment as of January 1, 2000.

Our net loss for the nine months ended September 30, 2001 was $47.8 million, or $1.15 per share (basic and diluted), compared with a net loss of $14.8 million, or $0.43 per share (basic and diluted), for the same period in 2000.

Liquidity and Capital Resources

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

In May 1997, we entered into a long-term collaboration agreement with Procter and Gamble. Procter & Gamble agreed over the first five years of the 1997 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 our research efforts related to the collaboration, of which we have received $56.6 million through September 30, 2001. In August 2000, Procter & Gamble made two non-recurring research progress payments to us totaling $3.5 million. Effective December 31, 2000, we and Procter & Gamble entered into a new long-term collaboration agreement, replacing the companies' 1997 agreement. The new agreement extends Procter & Gamble's obligation to fund Regeneron's research through December 2005, with no further research obligations by either party thereafter, and focuses the companies' collaborative research on therapeutic areas that are of particular interest to Procter & Gamble. Under the new agreement, beginning in the first quarter of 2001, research support from Procter & Gamble is $2.5 million per quarter, before adjustments for future inflation, through December 2005.

Our activities relating to BDNF and NT-3, as agreed upon by Amgen and us, are being compensated by Amgen-Regeneron Partners for services rendered, and we recognize these amounts as revenue. In January 2001, Amgen-Regeneron Partners discontinued all development of BDNF for the potential treatment of amyotrophic lateral sclerosis, or ALS. We and Amgen fund Amgen-Regeneron Partners through capital contributions, and must make equal payments in order to maintain equal ownership and equal sharing of any profits or losses from the partnership. Our aggregate capital contribution to Amgen-Regeneron Partners from the partnership's inception in June 1993 through September 30, 2001 was $57.9 million. For the remainder of 2001, no capital contributions to the partnership are expected, but additional contributions may be required, depending upon, among other things, whether and how Amgen-Regeneron Partners proceeds with the development of NT-3.

In connection with our agreement to collaborate with Sumitomo Pharmaceuticals in the research and development of BDNF in Japan, we received a research progress payment from Sumitomo Pharmaceuticals of $3.0 million (reduced by $0.3 million Japanese withholding tax) in April 2000. In addition, Sumitomo Pharmaceuticals has paid us $32.0 million through September 30, 2001 in connection with supplying BDNF for preclinical and clinical use. In light of the discontinuation of BDNF development for ALS, we do not expect to receive further payments from Sumitomo Pharmaceuticals for research progress payments, contract research and development, or contract manufacturing, other than any wind-down costs.

Our additions to property, plant, and equipment totaled $5.6 million for both the nine months ended September 30, 2001 and 2000. In connection with the purchase and renovation of our Rensselaer facility, we obtained financing of $2.0 million from the New York State Urban Development Corporation. The outstanding balance on this note of approximately $1.5 million was fully repaid in October 2001.

We expect 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. In September 2000, Immunex Corporation filed a request with the European Patent Office seeking the declaration of an Opposition regarding our European patent relating to Cytokine Traps. This is a legal challenge to the validity and scope of our patent and we may incur substantial expenses in defending the patent.

At September 30, 2001, we had $268.0 million in cash, cash equivalents, and marketable securities. As of September 30, 2001, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. We may seek additional funding through, among other things, future collaboration agreements and public or private financing. We cannot assure you that additional financing will be available to us or, if available, that it will be available on acceptable terms.

In April 2000, we completed a public offering of 2.6 million shares of Common Stock at a price of $29.75 per share and received proceeds, after commissions and

expenses, of $72.9 million. In August 2000, we sold 573,630 shares of Common Stock to Procter & Gamble at a price of $29.75 per share and received total proceeds of $17.1 million. The sale of stock to Procter & Gamble was made pursuant to a 1997 securities purchase agreement. In March 2001, we completed a public offering in which we issued 6.5 million shares of Common Stock at a price of $25.00 per share and received proceeds, after commissions and expenses, of $153.6 million. In April 2001, we sold an additional 130,000 shares of Common Stock pursuant to the underwriters' over-allotment option from the March 2001 public offering at a price of $25.00 per share and received proceeds, after commissions and expenses, of $3.1 million.

In October 2001, we issued $200 million aggregate principal amount of convertible senior subordinated notes in a private placement and received proceeds, after deducting the initial purchasers' discount and before out-of-pocket expenses, of $193.4 million. The notes bear interest at 5.5% per annum, payable semi-annually, and mature in 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. We may redeem the notes, in whole or in part, at any time before October 17, 2004 if the closing price of our Common Stock has exceeded 150% of the conversion price then in effect for a specified period of time. Upon any such redemption, we are required to pay interest that would have been due up through October 17, 2004. We may also redeem some or all of the notes at any time on or after October 17, 2004 if the closing price of our Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time. We pledged $31.6 million of U.S. government securities which will be sufficient upon receipt of scheduled principal and interest payments to provide for the payment in full of the first six scheduled interest payments on the notes when due.

We expect to incur substantial funding requirements for, among other things, research and development activities (including preclinical and clinical testing), expansion and validation of manufacturing facilities, and the acquisition of equipment. We currently anticipate that for the remainder of 2001 and 2002, approximately 50-70% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including AXOKINE, Pegylated AXOKINE, IL-1 Trap, IL-4/13 Trap, VEGF Trap, and the Angiopoietins; approximately 5-15% of our expenditures will be invested in expansion of our manufacturing facilities; approximately 10-30% of our expenditures will cover our basic research activities; approximately 5-15% of our expenditures will be directed toward the continued development of our novel technology platforms, including potential efforts to commercialize these technologies; and the remainder of our expenditures will be for general corporate purposes, including working capital. The amount we need to fund operations and the allocation of our resources will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of any collaborative research arrangements (including those with Procter & Gamble, Medarex, Emisphere Technologies, Inc., and Amgen). We believe that our existing capital resources will enable us to meet operating needs through

at least 2003. However, this is a forward-looking statement based on our current operating plan, and we cannot assure you that there will be no change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates.

Future Impact of Recently Issued Accounting Standards

The Financial Accounting Standards Board has recently issued Statement of Financial Accounting Standards, or SFAS, No. 141, *Business Combinations*, SFAS No. 142, *Goodwill and Other Intangible Assets*, SFAS No. 143, *Accounting for Obligations Associated with the Retirement of Long-Lived Assets*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which we will be required to adopt in future periods. Management believes that the future adoption of these accounting standards will not have a material impact on our financial statements.

Factors That May Affect Future Operating Results

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

- Delay, difficulty, or failure of our research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by us or others.

- Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, those with Procter & Gamble and Amgen) and the resulting loss of research or other funding could have a material adverse effect on us and our operations. A change of control of one or more of our material collaborators or licensees could also have a material adverse effect on us.

- Delay, difficulty, or failure of a clinical trial of any of our product candidates. A clinical trial can fail or be delayed as a result of many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining patients, lack of sufficient supplies of the product candidate, and the

failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol.

- In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our pharmaceutical candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune type" disease. Whether antibodies will be created can often not be predicted from preclinical experiments and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been successfully completed. Patients who have been treated with AXOKINE and NT-3 have developed antibodies.

- Delay, difficulty, or failure in obtaining regulatory approval (including approval of our facilities for production) for our products, including delays or difficulties in development because of insufficient proof of safety or efficacy.

- Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.

- Competitive or market factors that may cause use of our products to be limited or otherwise fail to achieve broad acceptance.

- The ability to obtain, maintain, and prosecute intellectual property rights and the cost of acquiring in-process technology and other intellectual property rights, either by license, collaboration, or purchase of another entity.

- Difficulties or high costs of obtaining adequate financing to fund the cost of developing product candidates.

- Amount and rate of growth of our general and administrative expenses, and the impact of unusual charges resulting from our ongoing evaluation of our business strategies and organizational structure.

- Failure of corporate partners to develop or commercialize successfully our products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between our corporate partners and us.

- Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology product in commercial quantities at reasonable costs and in compliance with applicable

quality assurance and environmental regulations and governmental permitting requirements.

- Difficulties in obtaining key raw materials and supplies for the manufacture of our product candidates.
- Failure of service providers upon whom we rely to carry out our clinical development programs, such as contract research organizations and third parties who fill and label our clinical supplies, to perform their contractual responsibilities. These failures could lead to delays in our clinical development programs.
- The costs and other effects of legal and administrative cases and proceedings (whether civil, such as product- or employment-related, or environmental, or criminal), settlements, and investigations; developments or assertions by or against us relating to intellectual property rights and licenses; the issuance and use of patents and proprietary technology by us and our competitors, including the possible negative effect on our ability to develop, manufacture, and sell our products in circumstances where we are unable to obtain licenses to patents which may be required for our products.
- Underutilization of our existing or new manufacturing facilities or of any facility expansions, resulting in inefficiencies and higher costs; start-up costs, inefficiencies, delays, and increased depreciation costs in connection with the start of production in new plants and expansions.
- Failure to have sufficient manufacturing capacity to make clinical supplies or commercial product in a timely and cost-competitive manner. Insufficient manufacturing capacity could delay clinical trials or limit commercial sale of marketed products.
- Health care reform, including reductions or changes in reimbursement available for prescription medications or other reforms.
- Difficulties in attracting and retaining key personnel.

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

Item 3. Quantitative and Qualitative Disclosure About Market Risk.

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes.

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

None

(b) Reports

Form 8-K: On October 12, 2001, we issued a press release announcing our intention to offer approximately $150 million of seven-year convertible senior subordinated notes in an offering pursuant to Rule 144A of the Securities Act of 1933.

Form 8-K: On October 12, 2001, we issued a press release announcing that we entered into a purchase agreement providing for the sale of $200 million aggregate principal amount of convertible senior subordinated notes due 2008, reflecting an increase in the size of the offering from $150 million.

Table of Contents

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 13, 2001

By: /s/ Murray A. Goldberg

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