



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, 2002

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  
(State or other jurisdiction of  
incorporation or organization)

13-3444607  
(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road  
Tarrytown, New York  
(Address of principal executive offices)

10591-6707  
(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, 2002:

Class of Common Stock	Number of Shares
Class A Stock, \$0.001 par value	2,500,581
Common Stock, \$0.001 par value	41,535,710

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**REGENERON PHARMACEUTICALS, INC.**

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**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****REGENERON PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2002 AND DECEMBER 31, 2001 (Unaudited)***(In thousands, except share data)*

	September 30, 2002	December 31, 2001
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 75,574	\$ 247,393
Marketable securities	207,976	126,796
Restricted marketable securities	16,341	10,890
Receivable due from The Procter & Gamble Company	2,631	2,665
Receivable due from Merck & Co., Inc.	1,886	63
Receivable due from Amgen-Regeneron Partners	4	247
Prepaid expenses and other current assets	3,259	2,159
Inventory	6,152	3,973
Total current assets	313,823	394,186
Marketable securities	30,987	32,420
Restricted marketable securities	10,496	20,884
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	56,138	39,448
Other assets	7,148	8,459
Total assets	\$ 418,592	\$ 495,397
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 24,376	\$ 14,830
Deferred revenue, current portion	8,041	6,766
Capital lease obligations, current portion	237	426
Total current liabilities	32,654	22,022
Deferred revenue	5,150	6,870
Capital lease obligations		150
Notes payable	200,000	200,000
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; 2,500,581 shares issued and outstanding in 2002		
2,562,689 shares issued and outstanding in 2001	3	3
Common Stock, \$.001 par value; 160,000,000 shares authorized; 41,526,657 shares issued and outstanding in 2002		
41,264,280 shares issued and outstanding in 2001	42	41
Additional paid-in capital	569,917	567,624
Unearned compensation	(1,516)	(2,789)
Accumulated deficit	(388,382)	(299,698)
Accumulated other comprehensive income	724	1,174
Total stockholders' equity	180,788	266,355
Total liabilities and stockholders' equity	\$ 418,592	\$ 495,397

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
<b>Revenues</b>				
Contract research and development	\$ 2,780	\$ 2,819	\$ 8,215	\$ 9,351
Contract manufacturing	3,786	2,661	8,861	8,221
	<u>6,566</u>	<u>5,480</u>	<u>17,076</u>	<u>17,572</u>
<b>Expenses</b>				
Research and development	34,294	25,039	90,471	61,440
Contract manufacturing	1,637	1,274	4,757	5,347
General and administrative	2,811	2,461	9,167	6,875
	<u>38,742</u>	<u>28,774</u>	<u>104,395</u>	<u>73,662</u>
Loss from operations	<u>(32,176)</u>	<u>(23,294)</u>	<u>(87,319)</u>	<u>(56,090)</u>
<b>Other income, net</b>				
Investment income	2,378	3,162	7,703	9,474
(Loss in) earnings from Amgen-Regeneron Partners	(1)	241	(2)	(1,056)
Interest expense	(3,017)	(40)	(9,066)	(130)
	<u>(640)</u>	<u>3,363</u>	<u>(1,365)</u>	<u>8,288</u>
Net loss	<u>(\$32,816)</u>	<u>(\$19,931)</u>	<u>(\$88,684)</u>	<u>(\$47,802)</u>
Net loss per share amounts, basic and diluted	<u>(\$0.75)</u>	<u>(\$0.46)</u>	<u>(\$2.02)</u>	<u>(\$1.15)</u>

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

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**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)**  
**For the nine months ended September 30, 2002**  
*(In thousands)*

	Class A Stock		Common Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	
Balance, December 31, 2001	2,563	\$ 3	41,264	\$41	\$567,624
Issuance of Common Stock in connection with exercise of stock options			174	1	1,467
Issuance of restricted Common Stock under Long-Term Incentive Plan			5		59
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			22		764
Conversion of Class A Stock to Common Stock	(62)		62		
Amortization of unearned compensation					
Issuance of stock options in consideration for consulting services					3
Net loss					
Change in net unrealized gain on marketable securities					
Balance, September 30, 2002	2,501	\$ 3	41,527	\$42	\$569,917

	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Loss
Balance, December 31, 2001	(\$2,789)	(\$299,698)	\$1,174	\$266,355	
Issuance of Common Stock in connection with exercise of stock options				1,468	
Issuance of restricted Common Stock under Long-Term Incentive Plan	(59)				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution				764	
Conversion of Class A Stock to Common Stock					
Amortization of unearned compensation	1,332			1,332	
Issuance of stock options in consideration for consulting services				3	
Net loss		(88,684)		(88,684)	(\$88,684)
Change in net unrealized gain on marketable securities			(450)	(450)	(450)
Balance, September 30, 2002	(\$1,516)	(\$388,382)	\$ 724	\$180,788	(\$89,134)

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

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**CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)**  
**(In thousands)**

	Nine months ended September 30,	
	2002	2001
<b>Cash flows from operating activities</b>		
Net loss	(\$88,684)	(\$47,802)
<b>Adjustments to reconcile net loss to net cash used in operating activities</b>		
Loss in Amgen-Regeneron Partners	2	1,056
Depreciation and amortization	6,405	4,267
Non-cash compensation expense	1,335	537
<b>Changes in assets and liabilities</b>		
Decrease in amounts due from The Procter & Gamble Company	34	4,407
(Increase) decrease in amounts due from Merck & Co., Inc.	(1,823)	1,113
Decrease in amounts due from Amgen-Regeneron Partners	243	891
Decrease in amounts due from Sumitomo Pharmaceuticals Company, Ltd.		3,877
Increase in prepaid expenses and other assets	(1,581)	(6,330)
Increase in inventory	(1,335)	(304)
Decrease in deferred revenue	(445)	(2,557)
Increase in accounts payable, accrued expenses, and other liabilities	6,352	1,179
Total adjustments	9,187	8,136
Net cash used in operating activities	(79,497)	(39,666)
<b>Cash flows from investing activities</b>		
Purchases of marketable securities	(199,217)	(120,766)
Sales or maturities of marketable securities	119,465	77,211
Purchases of restricted marketable securities	(5,500)	
Maturities of restricted marketable securities	11,000	
Capital expenditures	(19,199)	(5,623)
Net cash used in investing activities	(93,451)	(49,178)
<b>Cash flows from financing activities</b>		
Net proceeds from the issuance of stock	1,468	158,352
Principal payments on note payable		(50)
Capital lease payments	(339)	(462)
Net cash provided by financing activities	1,129	157,840
Net (decrease) increase in cash and cash equivalents	(171,819)	68,996
Cash and cash equivalents at beginning of period	247,393	30,978
Cash and cash equivalents at end of period	\$ 75,574	\$ 99,974

**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, 2001 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, 2001.

**2. Statement of Cash Flows**

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2002 and December 31, 2001 are \$5,904 and \$1,946, respectively, of accrued capital expenditures. 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 December 31, 2001 and 2000 are \$764 and \$477, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2002 and 2001, the Company contributed 21,953 and 17,484 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2002 and December 31, 2001 are \$2,433 and \$1,988, respectively, of accrued interest income. Included in marketable securities at September 30, 2001 and December 31, 2000 are \$2,276 and \$2,346, respectively, of accrued interest income.

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements****(Dollars in thousands, except per share data)****3. Inventories**

Inventories consist 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, 2002 and December 31, 2001 consist of the following:

	September 30, 2002	December 31, 2001
Raw materials	\$ 368	\$ 374
Work-in-process	626	227(2)
Finished products	5,158(1)	3,372
	<u>\$6,152</u>	<u>\$3,973</u>

(1) Net of reserves of \$810.

(2) Net of reserves of \$230.

**4. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses as of September 30, 2002 and December 31, 2001 consist of the following:

	September 30, 2002	December 31, 2001
Accounts payable	\$ 4,090	\$ 3,007
Accrued payroll and related costs	4,123	3,662
Accrued clinical trial expense	4,570	2,583
Accrued expenses, other	6,551	3,286
Interest payable on convertible notes	5,042	2,292
	<u>\$24,376</u>	<u>\$14,830</u>

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements****(Dollars in thousands, except per share data)****5. Comprehensive Loss**

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the nine months ended September 30, 2002 and 2001, the components of comprehensive loss are:

	Nine Months Ended September 30,	
	2002	2001
Net loss	(\$88,684)	(\$47,802)
Change in net unrealized gain on marketable securities	(450)	1,177
Total comprehensive loss	(\$89,134)	(\$46,625)

**6. Stock Compensation**

The Company awards shares of Restricted Stock under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Restrictions on these shares generally lapse with respect to 25% of the shares every six months over approximately 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 period that the restrictions lapse. For the three and nine months ended September 30, 2002, the Company recognized compensation expense related to Restricted Stock awards of \$453 and \$1,332, respectively. 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.

**7. 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, 2002 and 2001, the Company reported net losses and, 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:

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**Notes to Condensed Financial Statements**  
**(Dollars in thousands, except per share data)**

		Three Months Ended September 30,		
		Net Loss, in thousands (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2002:				
	Basic and Diluted	(\$32,816)	43,950	(\$0.75)
2001:				
	Basic and Diluted	(\$19,931)	43,648	(\$0.46)
		Nine Months Ended September 30,		
		Net Loss, in thousands (Numerator)	Shares, in thousands (Denominator)	Per Share Amount
2002:				
	Basic and Diluted	(\$88,684)	43,895	(\$2.02)
2001:				
	Basic and Diluted	(\$47,802)	41,530	(\$1.15)

Shares issuable upon the exercise of options and warrants, vesting of restricted stock awards, and conversion of convertible debt, 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,	
		2002	2001
Options:			
	Weighted Average Number, in thousands	9,483	7,467
	Weighted Average Exercise Price	\$21.38	\$19.22
Restricted Stock Awards:			
	Weighted Average Number, in thousands	73	34
Convertible Debt:			
	Weighted Average Number, in thousands	6,611	
	Conversion Price	\$30.25	

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**Notes to Condensed Financial Statements**  
**(Dollars in thousands, except per share data)**

	Nine Months Ended September 30,	
	2002	2001
Options and Warrants:		
Weighted Average Number, in thousands	9,459	7,542
Weighted Average Exercise Price	\$21.43	\$19.10
Restricted Stock Awards:		
Weighted Average Number, in thousands	89	37
Convertible Debt:		
Weighted Average Number, in thousands	6,611	
Conversion Price	\$30.25	

**8. 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.

The tables below present information about reported segments for the three and nine months ended September 30, 2002 and 2001.

	Three Months Ended September 30, 2002			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 2,780	\$3,786	—	\$ 6,566
Loss in Amgen-Regeneron Partners	1	—	—	1
Depreciation and amortization	1,909	—(1)	\$ 261	2,170
Interest expense	6	—	3,011	3,017
Net (loss) income	(34,332)	2,149	(633) <sup>(2)</sup>	(32,816)
Capital expenditures	10,864	—	—	10,864

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

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	—(1)	—	1,519
Interest expense	30	10	—	40
Net (loss) income	(24,470)	1,377	\$3,162(3)	(19,931)
Capital expenditures	1,597	—	—	1,597

Nine Months Ended September 30, 2002

	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 8,215	\$ 8,861	—	\$ 17,076
Loss in Amgen-Regeneron Partners	2	—	—	2
Depreciation and amortization	5,623	—(1)	\$ 782	6,405
Interest expense	32	2	9,032	9,066
Net (loss) income	(91,457)	4,102	(1,329) <sup>(2)</sup>	(88,684)
Capital expenditures	23,122	35	—	23,157
Total assets	54,666	12,564	351,362(4)	418,592

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	—(1)	—	4,267
Interest expense	94	36	—	130
Net (loss) income	(60,114)	2,838	\$ 9,474(3)	(47,802)
Capital expenditures	5,563	25	—	5,588
Total assets	35,890	8,998	273,725(4)	318,613

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

(2) Represents investment income, net of interest expense related to convertible notes issued in October 2001.

(3) Represents investment income.

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

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements****(Dollars in thousands, except per share data)****9. Legal Matters**

The Company, from time to time, has been subject to legal claims arising in connection with its business. While the ultimate results of the legal claims cannot be predicted with certainty, at September 30, 2002 there were no asserted claims against the Company which, in the opinion of management, if adversely decided would have a materially adverse effect on the Company's financial position, results of operations, and cash flows.

**10. Adjustment of Previously Reported Pro Forma Operating Results**

The Company measures the compensation costs associated with its stock option plan using the intrinsic value based method of accounting prescribed by APB Opinion No. 25, *Accounting for Stock issued to Employees*. In accordance with the Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, ("SFAS No.123"), the Company provides pro forma disclosure of the net loss and net loss per share as if the fair value based method of accounting had been applied ("SFAS No. 123 pro forma operating results").

The Company is adjusting its SFAS No. 123 pro forma operating results for the years ended December 31, 2001, 2000, and 1999. In August 2002, the Company discovered minor errors in the process used by the Company to value options for purposes of SFAS No. 123. The Company believes that the errors are immaterial, and the Company is not aware of any other adjustments to be made to the SFAS No. 123 pro forma operating results.

The adjustments are as follows:

	2001		2000		1999	
	As Reported	As Adjusted	As Reported	As Adjusted	As Reported	As Adjusted
Pro forma net loss (in thousands)	\$102,909	\$108,338	\$33,131	\$33,723	\$27,739	\$28,047
Pro forma net loss per share	\$ 2.45	\$ 2.57	\$ 0.95	\$ 0.96	\$ 0.89	\$ 0.90

The Company's financial results, as reported in its Statement of Operations and Balance Sheets for the years ended December 31, 2001, 2000, and 1999, are not affected by these adjustments.

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements**

**(Dollars in thousands, except per share data)**

**11. Future Impact of Recently Issued Accounting Standards**

The Financial Accounting Standards Board (“FASB”) has recently issued Statement of Financial Accounting Standards No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections as of April 2002*, and Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, 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.



## 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, nature, and success 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 medicines 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. Developing and commercializing new therapeutic drugs entails risk and significant expense. Since inception, we have not generated any sales or 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 our 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, which 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 and preclinical research programs. We currently retain sole ownership and marketing rights for each of these programs and 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 subjects. In the trial, AXOKINE was generally well tolerated and subjects treated with AXOKINE showed medically meaningful and statistically significant weight loss compared with those receiving placebo. In September 2001, we reported that subjects who completed 36 weeks of follow-up after cessation of AXOKINE 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 subjects. We began enrolling subjects in the initial pivotal trial in September 2001 and in January 2002 completed enrollment of approximately 2,000 subjects in 65 sites across the United States. This pivotal trial includes a twelve-month treatment period, which is expected to be completed in January 2003, in which subjects receive daily subcutaneous self-injections of placebo or AXOKINE. The treatment period is followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. In June 2002, we announced the initiation of a clinical trial to assess the safety and efficacy of AXOKINE in overweight and obese individuals with type 2 diabetes mellitus. In July 2002, we announced that we had completed enrollment for two additional trials, each of which includes approximately 300 subjects, that are designed to evaluate the safety of intermittent treatment with AXOKINE and to study maintenance of weight loss following short-term treatment regimens. Additional Phase III studies are expected to begin in 2003.
- **INTERLEUKIN-1 CYTOKINE TRAP (IL-1 Trap):** Protein-based drug candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. 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 subjects with rheumatoid arthritis. In January 2002, we reported positive preliminary results from the trial. Subjects treated with the IL-1 Trap experienced dose-dependent improvements in tender and swollen joints and CRP (C-Reactive Protein) levels, as well as the composite ACR (American College of Rheumatology) measure of disease activity. In July 2002, we announced the initiation of a dose-ranging Phase II trial, that will involve approximately 200 participants, to study the safety and efficacy of the IL-1 Trap in subjects with rheumatoid arthritis.
- **VEGF TRAP:** Protein-based drug candidate designed to bind Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF) and prevent its interaction with cell surface receptors. 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. In 2001, we initiated a dose-ranging Phase I clinical trial designed to assess the safety and tolerability of

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VEGF Trap in subjects with solid tumor malignancies and subjects with non-Hodgkin's lymphoma. This trial is currently in progress.

- **INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/13 Trap):** Protein-based drug candidate designed to bind the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines and prevent their interaction with cell surface receptors. IL-4 and IL-13 are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. We recently initiated a Phase I trial for the IL-4/13 Trap in subjects with mild to moderate asthma. This trial is a placebo-controlled, double-blind, dose escalation study to assess the safety and tolerability of the molecule.
- **PEGYLATED AXOKINE:** Chemically modified version of AXOKINE that is being evaluated for its potential to remain in the bloodstream longer than unmodified AXOKINE in obese subjects. Preliminary results of a Phase I trial demonstrate a long pharmacokinetic half-life, potentially compatible with once-per-week dosing regimens. In its current form, the molecule is not optimally absorbed into the blood stream and has caused unacceptable injection site reactions. We are currently working to develop an improved form of PegAXOKINE.
- **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. We have an active preclinical research program covering this family of growth factors. We have not yet selected a specific molecule to advance into clinical development or a specific indication for such 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, although there are no ongoing development activities for NT-3 at this time. In all of these research collaborations, we retain 50% of the commercialization rights.

### *Discussion of Third Quarter 2002 Activities*

In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese subjects. We announced in January 2002 that the initial trial was fully enrolled with approximately 2,000 subjects at 65 sites across the United States. This trial is a double-blind, randomized, placebo-controlled study. It has a twelve-month

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treatment period, which is expected to be completed in January 2003, in which subjects 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 is followed by a twelve-month open-label safety extension phase, during which all study subjects receive AXOKINE. Endpoints of the study are based on changes in body weight versus baseline during the treatment period.

During the second quarter of 2002, we initiated three additional studies in the AXOKINE Phase III program. Two of the studies were fully enrolled in July 2002 and are running concurrently. Each of these randomized, double-blind short-term treatment studies will assess the safety and efficacy of AXOKINE compared with placebo in approximately 300 subjects over defined dosing periods. Participants in the first study are being given AXOKINE or placebo for 6 months and will then be observed for another 6 months off-treatment. The companion study is treating subjects with AXOKINE or placebo for 3 months and will observe them for an additional 9 months off-treatment. The primary end-point of these studies is weight loss at the end of 12 months. At the end of the initial 12-month treatment and observation periods of the two studies, participants will receive an additional 6 months of treatment of which 3 months is on AXOKINE and 3 months on placebo. A follow-up evaluation will assess the safety and weight-loss effects of re-treatment with AXOKINE.

The third study, initiated in June 2002, will assess the safety and efficacy of AXOKINE in overweight and obese individuals with type 2 diabetes mellitus. In this double-blind, placebo-controlled study, participants are randomized into three treatment groups and given placebo or one of two AXOKINE doses (0.5 or 1.0 mcg/kg/day) for 12 weeks. At the end of the initial phase, all participants will receive AXOKINE for a 12-week extension period in two separate dose groups. This study involves approximately 160 overweight and obese subjects with type 2 diabetes and is being conducted at 24 sites within the United States. The trial will measure weight loss and explore the short-term effects of weight loss with AXOKINE on blood levels of insulin, glucose, and other glycemic parameters.

As part of the overall Phase III program, Regeneron plans to conduct additional confirmatory and ancillary studies of AXOKINE in obese and obese diabetic subjects. These studies, which are expected to begin in 2003, will vary in duration and size and are planned to be completed in 2004. The Phase III program is expected to enroll over 4,000 subjects in total.

In December 2000, we initiated a Phase I study of the IL-1 Trap to assess its safety and tolerability in subjects with rheumatoid arthritis. The placebo-controlled, double-blind, dose-escalation study was conducted at several centers in the United States and included a single dose phase and a multiple dose phase. In January 2002, we reported positive preliminary results from the trial. The preliminary results indicated that subjects treated with the IL-1 Trap experienced dose dependent improvements in tender and swollen joints and CRP levels as well as the composite ACR measure of disease activity. We also conducted a small pilot safety study of the IL-1 Trap at a single, fixed high dose

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of 100 mg compared with placebo. This study involved 14 subjects with active rheumatoid arthritis who received IL-1 Trap by weekly subcutaneous injections at the study sites over 6 weeks. The trial was not designed to measure disease activity. Preliminary results indicated that the IL-1 Trap was generally well tolerated with similar adverse events in the drug-treated and placebo-treated subjects. There were no drug-related serious adverse events.

In July 2002, we announced the initiation of a dose-ranging Phase II trial to study the safety and efficacy of the IL-1 Trap in subjects with rheumatoid arthritis. The trial is a randomized, placebo-controlled, double-blind study in subjects who have had an inadequate response to at least one disease-modifying anti-rheumatic medicine. The study will involve approximately 200 participants, who will be randomized equally into placebo or one of three fixed-dose groups (25, 50, or 100 milligrams) to receive self-administered, weekly subcutaneous injections. The double-blind treatment period is 12 weeks, and participants will also be evaluated for 10 weeks following treatment. The ACR20 criteria for improvement in rheumatoid arthritis as a function of IL-1 Trap dose is the primary end-point.

In July 2002, we entered into an agreement with Amgen and Immunex Corporation for a non-exclusive license to certain intellectual property rights which may be used in the development and commercialization of the IL-1 Trap. Amgen and Immunex agreed to grant the license as part of a consent agreement with the United States Federal Trade Commission in connection with Amgen's acquisition of Immunex. This agreement followed licensing arrangements with ZymoGenetics, Inc. and Tularik Inc., under which we obtained non-exclusive rights to patents for potential use in the IL-1 Trap program. We will be required to make royalty payments under these three license agreements on any future sales of the IL-1 Trap.

In November 2001, we initiated a Phase I clinical trial designed to assess the safety and tolerability of VEGF Trap in subjects with solid tumor malignancies and subjects with non-Hodgkin's lymphoma. The Phase I trial is an open-label study in subjects with advanced tumors and will evaluate the VEGF Trap in increasing dose levels. The study is being conducted at three clinical sites in the United States.

In July 2002, we announced that we had submitted an IND application to the FDA to initiate a clinical trial development program for a dual IL-4/13 Trap in adult subjects with mild to moderate asthma. We initiated a Phase I trial in October 2002. This placebo-controlled, double-blind study is designed to evaluate the safety and tolerability of increasing doses of the IL-4/13 Trap in adult subjects with mild to moderate asthma.

In June 2002, we initiated a Phase I placebo-controlled, double-blind, single-dose, dose-escalation study to assess the safety and pharmacokinetics of the Company's pegylated version of AXOKINE (PegAXOKINE) for the treatment of obesity. We developed this chemically modified version of AXOKINE to remain in the bloodstream longer than unmodified AXOKINE in obese subjects. Preliminary results of the Phase I trial demonstrate a long pharmacokinetic half-life, potentially compatible with once-per-

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week dosing regimens. In its current form, the molecule is not optimally absorbed into the blood stream and has caused unacceptable injection site reactions. We are currently working to develop an improved form of PegAXOKINE.

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, 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, VEGF Trap, IL-4/13 Trap, or Pegylated AXOKINE, 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 product candidates to treat human conditions or to be approved for marketing could have a material adverse impact on us. 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, 2002, we had a cumulative loss of \$388.4 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 clinical, manufacturing, and commercialization expenses and on the progress of our research and development efforts.

## Results of Operations

*Three months ended September 30, 2002 and 2001.* Our total revenue increased to \$6.6 million for the third quarter of 2002 from \$5.5 million for the same period in 2001. Contract research and development revenue, related primarily to our long-term collaboration agreement with Procter & Gamble, was \$2.8 million in both the third quarters of 2002 and 2001. Contract manufacturing revenue increased to \$3.8 million in the third quarter of 2002 from \$2.7 million for the same period in 2001, due primarily to the receipt of a non-recurring \$1.0 million payment from Merck & Co., Inc. related to services we provided in prior years in connection with our long-term agreement to manufacture a vaccine intermediate for Merck at our Rensselaer, New York facility. We shipped similar quantities of product to Merck in the third quarters of 2002 and 2001.

Our total operating expenses increased to \$38.7 million in the third quarter of 2002 from \$28.8 million for the same period in 2001. Research and development expenses increased to \$34.3 million in the third quarter of 2002 from \$25.0 million for the comparable period in 2001, due primarily to our increased clinical development activity, especially related to our Phase III clinical program for AXOKINE. In addition, research and development expenses increased as a result of added staffing to support our increased clinical development activity and expanded research programs and the enabling technology platforms supporting that research. Research and development expenses were 89% of total operating expenses in the third quarter of 2002, compared to 87% for the same period in 2001. Contract manufacturing expenses related to our long-term agreement with Merck increased to \$1.6 million in the third quarter of 2002 from \$1.3 million for the comparable period in 2001 due primarily to additional production runs. General and administrative expenses increased to \$2.8 million in the third quarter of 2002 from \$2.5 million for the same period of 2001, due primarily to additional administrative staffing to support the growth of the company and higher fees paid to outside service providers.

Investment income decreased to \$2.4 million in the third quarter of 2002 from \$3.2 million for the same period of 2001, due to lower effective interest rates on investment securities in 2002 compared to 2001. Our share of the loss in Amgen-Regeneron Partners was approximately \$1,000 for the third quarter of 2002 compared to earnings of \$0.2 million for the same period in 2001. The partnership is not currently conducting any clinical studies. The partnership's third quarter 2001 net income is attributable primarily to a \$0.8 million reduction of previously estimated costs to wind-down a completed clinical study. Interest expense increased \$3.0 million in the third quarter of 2002 compared to the same period in 2001, due to interest incurred on \$200.0 million of convertible senior subordinated notes issued in October 2001. These notes bear interest at 5.5% per annum, payable semi-annually.

Our net loss for the third quarter of 2002 was \$32.8 million, or \$0.75 per share (basic and diluted), compared to a net loss of \$19.9 million, or \$0.46 per share (basic and diluted), for the same period in 2001.

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*Nine months ended September 30, 2002 and 2001.* Our total revenue decreased to \$17.1 million for the nine months ended September 30, 2002 from \$17.6 million for the same period in 2001. Contract research and development revenue decreased to \$8.2 million for the nine months ended September 30, 2002 from \$9.4 million for the same period in 2001, due to the substantial completion of studies conducted on behalf of Amgen-Regeneron Partners. Contract manufacturing revenue, related primarily to our long-term agreement with Merck, increased to \$8.9 million in the first nine months of 2002 from \$8.2 million for the same period in 2001. In the third quarter of 2002, we received a non-recurring \$1.0 million payment related to services we provided in prior years in connection with the Merck agreement. This increase was partly offset by lower revenue because we shipped less product to Merck in the first nine months of 2002 than the comparable period of 2001. Certain quantities of product that we manufactured for Merck in the first nine months of 2002 will not be shipped until later this year or 2003. Contract manufacturing revenue and the related manufacturing expense are recognized as product is shipped.

Our total operating expenses increased to \$104.4 million for the nine months ended September 30, 2002 from \$73.7 million for the same period in 2001. Research and development expenses increased to \$90.5 million in the first nine months of 2002 from \$61.4 million for the comparable period in 2001, due primarily to our expanded clinical development activity, especially our Phase III clinical program for AXOKINE, which we initiated in July 2001. In addition, research and development expenses increased as a result of added staffing to support our increased clinical development activity and expanded research programs and the enabling technology platforms supporting that research. Research and development expenses were 87% of total operating expenses for the first nine months of 2002, compared to 83% for the same period in 2001. Contract manufacturing expenses related to our long-term agreement with Merck decreased to \$4.8 million for the nine months ended September 30, 2002 from \$5.3 million for the same period in 2001, primarily due to the above-described decrease in shipments of product to Merck and higher manufacturing costs in the first quarter of 2001. General and administrative expenses increased to \$9.2 million in the first nine months of 2002 from \$6.9 million for the same period of 2001, due primarily to additional administrative staffing to support the growth of the company, higher fees paid to outside service providers, and higher patent prosecution and legal expenses related to the expansion of our intellectual property portfolio.

Investment income decreased to \$7.7 million for the nine months ended September 30, 2002 from \$9.5 million for the same period of 2001, due to lower effective interest rates on investment securities in 2002 compared to 2001. Our share of the loss in Amgen-Regeneron Partners decreased to approximately \$2,000 in the first nine months of 2002 compared to \$1.1 million for the same period in 2001, due to the substantial completion of studies conducted on behalf of the partnership. Interest expense increased by \$8.9 million for the first nine months of 2002 compared to the same period in 2001, due to interest incurred on \$200.0 million of convertible senior subordinated notes issued in October 2001. These notes bear interest at 5.5% per annum, payable semi-annually.



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Our net loss for the nine months ended September 30, 2002 was \$88.7 million, or \$2.02 per share (basic and diluted), compared to a net loss of \$47.8 million, or \$1.15 per share (basic and diluted), for the same period in 2001.

### **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 Co., Ltd., Sumitomo Pharmaceuticals Company, Ltd., Merck, and Procter & Gamble, and investment income.

We and Procter & Gamble have a long-term collaboration agreement. Under our agreement, since the first quarter of 2001 and through December 2005, Procter & Gamble provides funding in support of our research efforts related to the collaboration of \$2.5 million per quarter, plus adjustments for inflation.

We are compensated by Amgen-Regeneron Partners for services we render on behalf of the partnership, and we recognize these amounts as revenue. We and Amgen fund Amgen-Regeneron Partners through capital contributions. If there are any further development costs of the partnership, we would expect to fund 50% of those costs in order to maintain equal ownership and equal sharing of the profits or losses of the partnership. Our aggregate capital contribution to Amgen-Regeneron Partners from the partnership's inception in June 1993 through September 30, 2002 was \$57.9 million. We do not expect to make capital contributions to the partnership in 2002 and during the third quarter of 2002 we and Amgen each withdrew \$0.5 million of capital from the partnership, since there are currently no ongoing development activities. Additional contributions may be required, if, among other things, Amgen-Regeneron Partners initiates any new development activities.

At September 30, 2002, we had \$341.4 million in cash, cash equivalents, marketable securities, and restricted marketable securities. Restricted marketable securities of \$26.8 million at September 30, 2002, consist of U.S. government securities that are pledged as collateral primarily with respect to initial interest payments due on the \$200.0 million of convertible senior subordinated notes due 2008 that we issued in October 2001. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of September 30, 2002, 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.

Our additions to property, plant, and equipment totaled \$23.2 million and \$5.6 million for the first nine months of 2002 and 2001, respectively. During March 2002, we entered into a new sublease for additional space at our Tarrytown, New York location, which expires in December 2005. During July 2002, we entered into a new lease for

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manufacturing and warehouse space adjacent to our Rensselaer, New York facility, which expires in July 2007 and contains renewal options to extend the lease for two additional five-year terms. During August 2002, we leased additional space at our Tarrytown location, with a term that expires in December 2006 and a renewal option to extend for an additional three-year period. Our base rent will increase by \$1.6 million per year for these additional premises in Tarrytown and Rensselaer, New York, excluding costs for utilities, real estate taxes, and operating expenses.

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 anticipate that full-year expenses for research and development will increase in 2002 by 30% or more over 2001 amounts. We currently anticipate that for the remainder of 2002, approximately 50-70% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including AXOKINE, IL-1 Trap, VEGF Trap, IL-4/13 Trap, PegAXOKINE, and the Angiopoietins; approximately 10-20% will be invested in expansion of our manufacturing facilities; approximately 10-20% will cover our basic research activities; approximately 5-15% 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 administrative expenses and working capital. During the remainder of 2002, we expect to incur approximately \$15 million in capital expenditures for our expanded manufacturing and research and development activities.

We anticipate that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

The amount we need to fund operations will depend on various factors, including 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 status of competitive products, 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). Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, and the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. 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

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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 (“FASB”) has recently issued Statement of Financial Accounting Standards No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections as of April 2002*, and Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, 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, the agreement with Procter & Gamble) 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 subjects, 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

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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. Subjects who have received AXOKINE and the IL-1 Trap in clinical trials 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 and manufacturing 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 products 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.

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- 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 litigation, such as product liability, commercial, employment-related, or environmental claims, or criminal litigation), 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, especially in areas where we have little experience such as sales and marketing.

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.

Other parties could allege to have blocking patents covering any of our product candidates in clinical and/or pre-clinical development. For example, we are aware of certain United States and foreign patents held by third parties relating to particular IL-4 and IL-13 receptors.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on

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commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing one or more of our product candidates, which could severely harm our business.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay license fees or royalties to take into account patent rights of third parties.

### **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.

### **Item 4. Controls and Procedures**

Within the 90 days prior to the date of this report (the “Evaluation Date”), we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined in Rules 13a-14(c) and 15d-14(c) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based upon the evaluation, our President and Chief Executive Officer along with our Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in timely alerting them to material information relating to Regeneron required to be included in our reports filed or submitted under the Exchange Act. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the Evaluation Date.

**PART II. OTHER INFORMATION**

**Item 6. Exhibits and Reports on Form 8-K**

(a) Exhibits

99.1 - Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports

None

**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.

Date: November 12, 2002

Regeneron Pharmaceuticals, Inc.

By: /s/ Murray A. Goldberg

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



## Certifications

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
  2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
  3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
    - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
    - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
    - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
    - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
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- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

By: /s/ Leonard S. Schleifer

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Leonard S. Schleifer, M.D., Ph.D.  
President and Chief Executive Officer

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I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
  2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
  3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
    - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
    - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
    - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
    - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
    - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
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6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

By: /s/ Murray A. Goldberg

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

**Certification of CEO and CFO Pursuant to  
18 U.S.C. Section 1350,  
As Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ending September 30, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.  
Chief Executive Officer  
November 12, 2002

/s/ Murray A. Goldberg

Murray A. Goldberg  
Chief Financial Officer  
November 12, 2002

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of § 18 of the Securities Exchange Act of 1934, as amended.