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, 2004

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 by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes (X) No ( )

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of October 31, 2004:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,358,373
Common Stock, $0.001 par value	53,383,323

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September 30, 2004

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2004 AND DECEMBER 31, 2003 (Unaudited)
(In thousands, except share data)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets		
Cash and cash equivalents	$ 105,047	$ 118,285
Marketable securities	168,120	164,576
Restricted marketable securities	5,548	10,913
Accounts receivable	24,866	15,529
Prepaid expenses and other current assets	3,391	1,898
Inventory	4,266	9,006
Total current assets	311,238	320,207
Marketable securities	82,469	72,792
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	73,942	80,723
Other assets	5,036	5,833
Total assets	$ 472,685	$ 479,555
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 20,284	$ 18,933
Deferred revenue, current portion	15,616	40,173
Loan payable to Novartis Pharma AG		13,817
Total current liabilities	35,900	72,923
Deferred revenue	57,876	68,830
Notes payable	200,000	200,000
Other long-term liabilities	36	159
Total liabilities	293,812	341,912
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; 2,358,373 shares issued and outstanding in 2004 2,365,873 shares issued and outstanding in 2003	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; 53,228,223 shares issued and outstanding in 2004 53,165,635 shares issued and outstanding in 2003	53	53
Additional paid-in capital	673,635	673,118
Unearned compensation	(1,989)	(4,101)
Accumulated deficit	(492,626)	(531,533)
Accumulated other comprehensive (loss) income	(202)	104
Total stockholders' equity	178,873	137,643
Total liabilities and stockholders' equity	$ 472,685	$ 479,555

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,	
	2004	2003	2004	2003
Revenues				
Contract research and development	$ 25,621	$ 10,882	$ 94,377	$ 28,245
Research progress payments			17,770	
Contract manufacturing	10,898	6,510	14,780	7,980
	36,519	17,392	126,927	36,225
Expenses				
Research and development	32,828	34,650	101,306	102,757
Contract manufacturing	8,986	4,844	11,740	5,769
General and administrative	4,184	3,601	12,209	10,548
	45,998	43,095	125,255	119,074
Income (loss) from operations	(9,479)	(25,703)	1,672	(82,849)
Other income (expense)				
Other contract income			42,750	
Investment income	1,417	1,285	3,646	3,594
Interest expense	(3,014)	(2,982)	(9,161)	(8,826)
	(1,597)	(1,697)	37,235	(5,232)
Net income (loss)	($ 11,076)	($ 27,400)	$ 38,907	($ 88,081)
Net income (loss) per share:				
Basic	($ 0.20)	($ 0.52)	$ 0.70	($ 1.80)
Diluted	($ 0.20)	($ 0.52)	$ 0.69	($ 1.80)
Weighted average shares outstanding:				
Basic	55,468	52,902	55,378	48,926
Diluted	55,468	52,902	56,295	48,926

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, 2004
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation
	Shares	Amount	Shares	Amount		
Balance, December 31, 2003	2,366	$ 2	53,166	$53	$673,118	($4,101)
Issuance of Common Stock in connection with exercise of stock options			113		683	
Repurchase of Common Stock from Merck & Co., Inc.			(109)		(888)	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan, net of issuances			(13)		(195)	195
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			64		917	
Conversion of Class A Stock to Common Stock	(8)		8			
Amortization of unearned compensation						1,917
Net income						
Change in net unrealized gain (loss) on marketable securities						
Balance, September 30, 2004	2,358	$ 2	53,229	$53	$673,635	($1,989)

[Additional columns below]

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

	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Income
Balance, December 31, 2003	($531,533)	$ 104	$137,643	
Issuance of Common Stock in connection with exercise of stock options			683	
Repurchase of Common Stock from Merck & Co., Inc.			(888)	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan, net of issuances				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			917	
Conversion of Class A Stock to Common Stock				
Amortization of unearned compensation			1,917	
Net income	38,907		38,907	$38,907
Change in net unrealized gain (loss) on marketable securities		(306)	(306)	(306)
Balance, September 30, 2004	($492,626)	($ 202)	$178,873	$38,601

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, 2004	2003
Cash flows from operating activities		
Net income (loss)	$ 38,907	($ 88,081)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities		
Depreciation and amortization	11,446	8,623
Non-cash compensation expense	1,917	1,954
Non-cash expense related to a license agreement		1,216
Forgiveness of loan payable to Novartis Pharma AG, inclusive of accrued interest	(17,770)	
Changes in assets and liabilities		
Increase in accounts receivable	(9,337)	(5,180)
(Increase) decrease in prepaid expenses and other assets	(2,338)	617
Decrease (increase) in inventory	5,601	(22)
(Decrease) increase in deferred revenue	(35,511)	98,902
Increase in accounts payable, accrued expenses, and other liabilities	2,375	4,267
Total adjustments	(43,617)	110,377
Net cash (used in) provided by operating activities	(4,710)	22,296
Cash flows from investing activities		
Purchases of marketable securities	(242,571)	(85,416)
Purchases of restricted marketable securities	(11,076)	(11,024)
Sales or maturities of marketable securities	229,768	200,936
Maturities of restricted marketable securities	16,576	16,523
Capital expenditures	(4,847)	(28,371)
Net cash (used in) provided by investing activities	(12,150)	92,648
Cash flows from financing activities		
Net proceeds from issuances of Common Stock	683	94,516
Repurchase of Common Stock	(888)	
Borrowings under loan payable	3,827	9,230
Capital lease payments		(150)
Net cash provided by financing activities	3,622	103,596
Net (decrease) increase in cash and cash equivalents	(13,238)	218,540
Cash and cash equivalents at beginning of period	118,285	80,077
Cash and cash equivalents at end of period	$ 105,047	$298,617

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

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unless otherwise noted, 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, 2003 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, 2003.

2. Per Share Data

The Company's basic net income (loss) per share amounts have been computed by dividing net income or loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock and the common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the treasury stock method when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's outstanding convertible senior subordinated notes, which are included under the if-converted method when dilutive. For the three months ended September 30, 2004 and the three and nine months ended September 30, 2003, the Company reported a net loss 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 income (loss) per share are as follows:

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months ended September 30,	
	2004	**2003**
Net loss (Numerator):	($11,076)	($27,400)
Weighted-average shares, in thousands (Denominator):	55,468	52,902
Basic and diluted net loss per share	($ 0.20)	($ 0.52)

	Nine Months ended September 30,	
	2004	**2003**
Net income (loss) (Numerator)	$38,907	($88,081)
Shares, in thousands (Denominator):		
Weighted-average shares for basic per share calculations	55,378	48,926
Effect of stock options	876	
Effect of restricted stock awards	41	
Adjusted weighted-average shares for diluted per share calculations	56,295	48,926
Basic net income (loss) per share	$ 0.70	($ 1.80)
Diluted net income (loss) per share	$ 0.69	($ 1.80)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the September 30, 2004 and 2003 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30, 2004	2003
Stock Options:		
Weighted average number, in thousands	13,015	11,133
Weighted average exercise price	$ 20.28	$ 21.59
Restricted Stock:		
Weighted average number, in thousands	196	125
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

	Nine months ended September 30,	
	2004	**2003**
Stock Options:		
Weighted average number, in thousands	10,141	11,332
Weighted average exercise price	$ 23.85	$ 21.44
Restricted Stock:		
Weighted average number, in thousands	3	158
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

3. Stock-based Employee Compensation

The accompanying financial position and results of operations of the Company have been prepared in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees.*

The following tables illustrate the effect on the Company's net income (loss) and net income (loss) per share had compensation costs for the Company's stock-based incentive plans been determined in accordance with the fair value based method of accounting for stock-based compensation as prescribed by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation.*

	Three months ended September 30,	
	2004	**2003**
Net loss, as reported	($11,076)	($ 27,400)
Add: Stock-based employee compensation expense included in reported net loss	618	822
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(8,655)	(11,341)
Pro forma net loss	($19,113)	($ 37,919)
Net loss per share amounts, basic and diluted:		
As reported	($ 0.20)	($ 0.52)
Pro forma	($ 0.34)	($ 0.72)

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

	Nine months ended September 30,	
	2004	**2003**
Net income (loss), as reported	$ 38,907	($ 88,081)
Add: Stock-based employee compensation expense included in reported net income (loss)	1,917	1,954
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(27,464)	(33,923)
Pro forma net income (loss), basic	$ 13,360	($120,050)
Basic net income (loss) per share amounts:		
As reported	$ 0.70	($ 1.80)
Pro forma	$ 0.24	($ 2.45)
Diluted net income (loss) per share amounts:		
As reported	$ 0.69	($ 1.80)
Pro forma	$ 0.24	($ 2.45)

For the purpose of the pro forma calculation, the fair value of each option granted from the Company's stock-based incentive plans during the three and nine months ended September 30, 2004 and 2003 was estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average fair value of the options granted during the three months ended September 30, 2004 and 2003 was $6.72 and $14.43, respectively. The weighted-average fair value of the options granted during the nine months ended September 30, 2004 and 2003 was $9.68 and $13.96, respectively. The following tables summarize the assumptions used in computing the fair value of option grants.

	Three months ended September 30,	
	2004	**2003**
Expected volatility	80%	80%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.95%-4.55%	3.02%-3.90%

	Nine months ended September 30,	
	2004	**2003**
Expected volatility	80%	80%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.38%-4.55%	3.01%-4.01%

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

Under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan, the Company awards shares of restricted stock. 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 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 months ended September 30, 2004 and 2003, the Company recognized compensation expense related to restricted stock awards of $618 and $559, respectively. For the nine months ended September 30, 2004 and 2003, the Company recognized compensation expense related to restricted stock awards of $1,917 and $1,691, respectively.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2004 and December 31, 2003 are $648 and $752, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2003 and December 31, 2002 are $694 and $13,490, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2003 and 2002 are $917 and $747, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2004 and 2003, the Company contributed 64,333 and 42,543 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2004 and December 31, 2003 are $1,602 and $878, respectively, of accrued interest income. Included in marketable securities at September 30, 2003 and December 31, 2002 are $437 and $2,013, respectively, of accrued interest income.

5. Accounts Receivable

Accounts receivable as of September 30, 2004 and December 31, 2003 consist of the following:

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

	September 30, 2004	December 31, 2003
Receivable from Aventis, a part of the sanofi aventis Group	$20,222	$ 8,917
Receivable from Novartis Pharma AG	—	3,177
Receivable from The Procter & Gamble Company	2,753	2,670
Receivable from Merck & Co., Inc.	1,891	765
	$24,866	$15,529

6. Inventories

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

Inventories as of September 30, 2004 and December 31, 2003 consist of the following:

	September 30, 2004	December 31, 2003
Raw materials	$ 404	$ 388
Work-in-process	609(1)	—(2)
Finished products	3,253	8,618
	$4,266	$9,006

(1) Net of reserves of $256.
(2) Net of reserves of $195.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2004 and December 31, 2003 consist of the following:

	September 30, 2004	December 31, 2003
Accounts payable	$ 5,185	$ 3,878
Accrued payroll and related costs	5,511	5,125
Accrued clinical trial expense	2,136	3,876
Accrued expenses, other	2,410	3,762
Interest payable on convertible notes	5,042	2,292
	$20,284	$18,933

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

8. Comprehensive Income (Loss)

Comprehensive income (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 income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. For the three months ended September 30, 2004 and 2003, the components of comprehensive loss are:

	Three months ended September 30,	
	2004	2003
Net loss	($11,076)	($27,400)
Change in net unrealized gain (loss) on marketable securities	9	(168)
Total comprehensive loss	($11,067)	($27,568)

For the nine months ended September 30, 2004 and 2003, the components of comprehensive income (loss) are:

	Nine months ended September 30,	
	2004	2003
Net income (loss)	$38,907	($88,081)
Change in net unrealized gain (loss) on marketable securities	(306)	(415)
Total comprehensive income (loss)	$38,601	($88,496)

9. Collaboration Agreement – Novartis Pharma AG

In March 2003, the Company entered into a collaboration agreement with Novartis Pharma AG (“Novartis”) to jointly develop and commercialize the Company’s Interleukin-1 Trap (“IL-1 Trap”). In connection with this agreement, Novartis made a non-refundable up-front payment of $27.0 million and purchased $48.0 million of newly issued unregistered shares of the Company’s Common Stock.

Development expenses incurred in 2003 were shared equally by the Company and Novartis. Regeneron funded its share of 2003 development expenses through loans from Novartis. In March 2004, Novartis forgave its outstanding loans to Regeneron totaling $17.8 million, including accrued interest, based on Regeneron’s achieving a pre-defined development milestone, which was recognized as a research progress payment.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

In February 2004, Novartis provided notice of its intention not to proceed with the joint development of the IL-1 Trap. In March 2004, Novartis agreed to pay the Company $42.75 million to satisfy its obligation to fund development costs for the IL-1 Trap for the nine month period following its notification and for the two months prior to that notice. The Company recorded the $42.75 million as other contract income in the first quarter of 2004. In addition, the Company recognized contract research and development revenue of $22.1 million, which represents the remaining amount of the March 2003 up-front payment from Novartis that had previously been deferred. Regeneron and Novartis each retain rights under the collaboration agreement to elect to collaborate in the future on the development and commercialization of certain other IL-1 antagonists.

10. Repurchase of Common Stock

On August 19, 2004, the Company repurchased and subsequently retired 109,450 shares of Regeneron Common Stock held by Merck that were issued to Merck in August 2003 in connection with a patent license agreement. The shares were acquired for a purchase price of $888 based on the fair market value of the shares on August 19, 2004. Regeneron also made a cash payment of $612 to Merck as required under the patent license agreement.

11. Segment Reporting

The Company’s operations are 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 (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements and (ii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology.

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 pediatric vaccine under a long-term manufacturing agreement.

The table below presents information about reported segments for the three and nine months ended September 30, 2004 and 2003.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended September 30, 2004			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 25,621	$10,898	—	$ 36,519
Depreciation and amortization	3,615	—(1)	$ 261	3,876
Interest expense	—	—	3,014	3,014
Net (loss) income	(11,391)	1,912	(1,597)(2)	(11,076)
Capital expenditures	1,844	—	—	1,844

	Three months ended September 30, 2003			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 10,882	$6,510	—	$ 17,392
Depreciation and amortization	3,395	—(1)	$ 261	3,656
Interest expense	58	—	2,924	2,982
Net (loss) income	(27,427)	1,666	(1,639)(2)	(27,400)
Capital expenditures	2,742	—	—	2,742

	Nine months ended September 30, 2004			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$112,147	$14,780	—	$126,927
Depreciation and amortization	10,663	—(1)	$ 783	11,446
Interest expense	126	—	9,035	9,161
Other contract income	42,750	—	—	42,750
Net income (loss)	41,256	3,040	(5,389)(2)	38,907
Capital expenditures	4,743	—	—	4,743
Total assets	94,658	8,416	369,611(3)	472,685

	Nine months ended September 30, 2003			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 28,245	$ 7,980	—	$ 36,225
Depreciation and amortization	7,840	—(1)	$ 783	8,623
Interest expense	66	—	8,760	8,826
Net (loss) income	(85,126)	2,211	(5,166)(2)	(88,081)
Capital expenditures	15,596	—	—	15,596
Total assets	88,543	12,067	399,891(3)	500,501

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

(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 primarily related to convertible notes issued in October 2001.
(3) Includes cash and cash equivalents, marketable securities, restricted marketable securities, prepaid expenses and other current assets, and other assets.

12. Income Taxes

The Company currently expects to recognize a tax loss for the year ended December 31, 2004. Accordingly, no provision for income taxes has been recorded in the accompanying financial statements.

13. Legal Matters

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of the Company's officers and directors in the United States District Court for the Southern District of New York. A consolidated amended class action complaint was filed in October 2003. The complaint, which purports to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, alleges that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE®, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. The Company's management believes that the complaint is without merit, and in December 2003 the Company filed a motion to dismiss the lawsuit. The ultimate outcome of this matter cannot presently be determined. Accordingly, no provision for any liability that may result upon the resolution of this matter has been made in the accompanying financial statements.

The Company, from time to time, has been subject to other legal claims arising in connection with its business. While the ultimate results of the legal claims cannot be predicted with certainty, at September 30, 2004 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.

14. Future Impact of Recently Issued Accounting Standards

In April 2004, the Emerging Issues Task Force issued Statement No. 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share* (EITF 03-6). EITF 03-6 addresses a number of questions regarding the

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements
(Unless otherwise noted, dollars in thousands, except per share data)

computation of earnings per share ("EPS") by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-6 defines participation rights based solely on whether the holder would be entitled to receive any dividends if the entity declared them during the period and requires the use of the two-class method for computing basic EPS when participating convertible securities exist. In addition, EITF 03-6 expands the use of the two-class method to encompass other forms of participating securities and is effective for fiscal periods beginning after March 31, 2004. Since the Company has no participating securities, the Company's adoption of EITF 03-6 did not have an impact on the Company's financial statements.

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

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 success and 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 sources and 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 "Risk Factors" 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. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. Our clinical and preclinical pipeline includes product candidates for the treatment of cancer, diseases of the eye, rheumatoid arthritis and other inflammatory conditions, allergies, asthma, obesity, and other diseases and disorders. Developing and commercializing new medicines entails significant risk and 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 basic scientific research and discovery-enabling 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 serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. These platforms are designed to discover specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Here is a summary of the clinical status of our clinical candidates as of September 30, 2004:

- **VEGF TRAP:** Protein-based product candidate designed to bind Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage. In 2001, we initiated a dose-escalation phase 1 clinical trial designed to assess the safety and tolerability of the VEGF Trap in subjects with advanced solid tumor malignancies. The preliminary results of this study were

announced at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2004 and we updated these results in a poster session at the 16th Annual EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in September 2004. The phase 1 trial was an open label, dose-escalation study conducted at three sites in the United States. The study enrolled and treated 38 patients with incurable, relapsed or refractory solid tumors, with subcutaneous injections of VEGF Trap. In total, the trial enrolled patients with 15 different types of cancer. Preliminary results of this study indicated that:

- the VEGF Trap was generally well-tolerated at the dose levels studied, and
- circulating levels of the VEGF Trap at the highest dose (1.6 mg/kg per week) were consistent with levels observed to be effective in preclinical models.

Detailed results of the trial are expected to be submitted for publication in a peer-reviewed journal once all patients complete the extended treatment phase available to patients who maintained stable disease after the initial 10-week treatment period and the full results of the extension phase have been analyzed.

During the third quarter of 2004, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for a specific niche cancer indication. As a result of the FDA's decision, Regeneron and Aventis, a part of the sanofi-aventis Group, plan to initiate a clinical trial in that indication in 2005.

A second phase 1 trial, which commenced in April 2004, is studying higher VEGF Trap exposures through intravenous administration. This study is also designed to evaluate the safety, tolerability, and pharmacokinetics of intravenous VEGF Trap in advanced cancer patients.

The VEGF Trap clinical development program has been expanded by initiating two separate phase 1 clinical trials of the VEGF Trap for the potential treatment of certain eye diseases. The first trial includes patients with the neovascular or "wet" form of age-related macular degeneration (AMD) a major cause of severe vision impairment and blindness in adults over the age of 55. Regeneron and Aventis have also started a phase 1 trial of the VEGF Trap delivered systemically by intravenous injections in patients with diabetic macular edema (DME). DME is a complication of diabetic retinopathy, a disease affecting the blood vessels of the retina. Diabetic retinopathy, in its late stages, can cause multiple problems involving blood vessels, including excess blood vessel growth. A major cause of vision loss in patients with diabetes, DME affects nearly 500,000 people in the United States. In addition to existing programs, we will also explore the possibility of studying the use of the VEGF Trap delivered through intravitreal administration.

In September 2003, we entered into a collaboration agreement with Aventis to jointly develop and commercialize the VEGF Trap in multiple oncology, ophthalmology, and possibly other indications throughout the world with the exception of Japan, where product rights remain with us. Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by Aventis. If the collaboration becomes profitable, we will reimburse Aventis

for 50 percent of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option.

- **INTERLEUKIN-1 TRAP (IL-1 Trap):** Protein-based product 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 an important role in rheumatoid arthritis and other inflammatory diseases. In October 2003, we announced that the IL-1 Trap demonstrated evidence of clinical activity and safety in patients with rheumatoid arthritis (RA) in a phase 2 dose-ranging study in approximately 200 patients. Patients treated with the highest dose, 100 milligrams of the IL-1 Trap, exhibited non-statistically significant improvements in the proportion of American College of Rheumatology (ACR) 20 responses versus placebo, the primary endpoint of the trial. Patients treated with the IL-1 Trap also exhibited improvements in secondary endpoints of the trial. The IL-1 Trap was generally well tolerated and was not associated with any serious drug-related adverse events.

  We plan to initiate additional studies of the IL-1 Trap in patients with rheumatoid arthritis in the next twelve months. The studies will be conducted in a larger patient population, testing higher doses and for a longer period of time than in the previous phase 2 trial. In addition, we intend to conduct studies of the IL-1 Trap in a variety of other diseases, such as osteoarthritis and cardiovascular disease, where interleukin-1 may play an important role. We have developed new product formulations that would allow delivery of higher doses of IL-1 Trap either through subcutaneous or intravenous administration. Initial, single-dose tolerability studies in healthy volunteers have been completed successfully and we plan to evaluate the new formulations in subsequent studies commencing in the fourth quarter of 2004.

  In March 2003, we began collaborating with Novartis Pharma AG on the development of the IL-1 Trap. On February 27, 2004, Novartis provided notice of its intention not to proceed with the joint development of the IL-1 Trap. In March 2004, Novartis agreed to pay us $42.75 million to satisfy its obligation to fund development costs for the nine month period following its notification and for the two months prior to that notice. Novartis paid us the $42.75 million in April 2004. All rights to the IL-1 Trap have reverted to Regeneron. Novartis and we retain rights under the collaboration agreement to elect to collaborate in the future on the development and commercialization of certain other IL-1 antagonists. In March 2004, we also achieved a pre-defined development milestone and Novartis forgave all its outstanding loans to us, totaling $17.8 million.

- **INTERLEUKIN-4/INTERLEUKIN-13 TRAP (IL-4/13 Trap):** Protein-based product candidate designed to bind both 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. In October 2002, we initiated a phase 1 trial for the IL-4/13 Trap in adult subjects with mild to moderate asthma. This placebo-controlled, double-blind, dose escalation study was designed to assess the safety and tolerability of the IL-4/13 Trap delivered by subcutaneous injections. The trial was completed in the first quarter of

2004, and the results were presented at a scientific conference during the second quarter of 2004. The IL-4/13 Trap was generally safe and well tolerated at the doses tested in this phase 1 trial. We plan to conduct additional studies to evaluate the safety and potential efficacy of the IL-4/13 Trap.

- **AXOKINE®:** Protein-based product candidate designed to act on the brain region regulating appetite and energy expenditure. AXOKINE is being developed for the treatment of obesity. In March 2003, we reported data from the 12-month treatment period of our initial phase 3 pivotal trial of AXOKINE. The double-blind treatment period in this study was followed by a twelve-month open-label extension phase, during which all study subjects received AXOKINE. The extension phase was completed in the first quarter of 2004. In the third quarter of 2004, we completed two randomized double-blind trials that were designed to evaluate the safety of intermittent treatment of AXOKINE and to study maintenance of weight loss following short-term treatment regimens. Participants in the two trials were given AXOKINE or placebo for three or six months and then observed for another six or nine months off-treatment. At the end of the initial 12-month treatment and observation period of the two studies, participants again received AXOKINE or placebo for a brief retreatment period. Each study included approximately 300 obese or overweight subjects. Subjects treated with AXOKINE lost more weight on average than those treated with placebo. However, these trials were designed before we had access to the data from the completed phase 3 AXOKINE trial and, therefore, did not enroll enough patients to detect a difference in the proportion of AXOKINE versus placebo treated patients who lost 5% of their initial body weight after twelve months. The preliminary findings from the studies were as follows:

  - Intermittent AXOKINE treatment appeared to be safe and generally well tolerated.

  - In the intermittent treatment trial where participants were given AXOKINE or placebo for six months, and then observed for another six months off-treatment, a higher proportion of AXOKINE treated subjects lost 5% of their initial body weight at twelve months compared to placebo-treated subjects (24.5% vs. 16.9%, p= 0.11). Moreover, after the six-month treatment period, participants receiving AXOKINE experienced a greater average weight loss than those receiving placebo (3.96 kg vs. 2.27 kg, p = .004), and this superiority of AXOKINE over placebo in weight loss was maintained at month twelve following the six-month off-treatment period (2.86kg vs. 1.41 kg, p=.047).

  - In the intermittent treatment trial where participants were given AXOKINE or placebo for three months, and then observed for another nine months off-treatment, a higher proportion of AXOKINE treated subjects lost 5% of their initial body weight at twelve months compared to placebo-treated subjects (17.4% versus 14.1%, p=0.5). Moreover, after the three-month treatment period, participants receiving AXOKINE experienced a greater average weight loss than those receiving placebo (2.73 kg vs. 1.71 kg, p = .022).

  We are continuing research on AXOKINE and evaluating its commercial potential. No new phase 3 clinical trials of AXOKINE are planned at this time.

In addition to our clinical programs, we have research programs focused on angiogenesis, metabolic diseases, muscle atrophy and related disorders, inflammatory conditions, and other diseases and disorders. We also use our Velocigene® and Trap technology platforms to discover and develop new product candidates and are developing our Velocimmune™ platform to create fully human, therapeutic antibodies.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any 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 research and development and obtaining regulatory approval from the FDA and 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 uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2004, we have had a cumulative loss of $492.6 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. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap, IL-1 Trap, IL-4/13 Trap, and AXOKINE; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any.

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 progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our four clinical programs, 2004 clinical events and plans anticipated for the next twelve months include:

Product Candidate	Nine Months ended September 30, 2004 Events	Next Twelve-Month Plans
VEGF Trap	• Completed phase 1 subcutaneous single-agent trial in cancer • Commenced phase 1 intravenous single-agent trial in cancer • Commenced phase 1 trial in neovascular age-related macular degeneration • Commenced phase 1 intravenous single-agent trial in diabetic macular edema	• Commence additional single-agent and combination trials in cancer • Commence additional studies in eye diseases

Product Candidate	Nine Months ended September 30, 2004 Events	Next Twelve-Month Plans
IL-1 Trap	• Planned for phase 2 trial in rheumatoid arthritis • Completed treatment phase of single-dose patient tolerability studies to evaluate new formulations	• Commence additional trials in rheumatoid arthritis • Commence clinical trial in osteoarthritis • Commence exploratory proof of concept trials in other indications • Evaluate IL-1 Trap in other inflammatory conditions
IL-4/13 Trap	• Completed phase 1 trial in asthma	• Commence clinical trial in asthma or other indication
AXOKINE	• Completed intermittent treatment trials • Additional research and development and market research activities	• Make decision on further development of AXOKINE • No new phase 3 trials planned at this time

Results of Operations

Three Months Ended September 30, 2004 and 2003

Revenues:

Revenues in the three months ended September 30, 2004 and 2003 consist of the following:

	(In millions)	
	2004	2003
Contract research & development revenue		
Aventis	$22.1	$ 2.6
Novartis	—	5.2
Procter & Gamble	2.8	2.7
Other	0.7	0.4
Total contract research & development revenue	25.6	10.9
Contract manufacturing revenue	10.9	6.5
Total revenue	$36.5	$17.4

Our total revenue increased to $36.5 million in the third quarter of 2004 from $17.4 million for the same period in 2003 primarily from revenue related to our collaboration with Aventis on the VEGF Trap, which commenced in September 2003. Contract research and development revenue from collaborators consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non refundable, up-front payments. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). In the third quarter of 2004 and 2003, in connection with the collaboration with Aventis, we recognized $19.4 million and $1.7 million,

respectively, in reimbursement for research and development expenses and $2.7 million and $0.9 million, respectively, in revenue related to an $80.0 million up-front non-refundable payment which was received in September of 2003. In the third quarter of 2003, in connection with our collaboration agreement with Novartis on the IL-1 Trap, we recognized $3.9 million in reimbursement for development expenses and $1.3 million in revenue related to a $27.0 million up-front non-refundable payment. In the first quarter of 2004, Novartis provided notice of its intention not to proceed with the joint development of the IL-1 Trap. As a result, we do not expect to recognize any future contract research and development revenue from Novartis.

Contract manufacturing revenue relates primarily to our long-term agreement with Merck & Co., Inc. to manufacture a vaccine intermediate at our Rensselaer, New York facility. This agreement expires in October 2005, unless extended by mutual agreement. Contract manufacturing revenue increased to $10.9 million in the third quarter of 2004 from $6.5 million for the same period in 2003, principally from an increase in product shipments to Merck in 2004 compared to the same period in 2003. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in the third quarter of 2004 and 2003 was $2.4 million and $1.3 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. This deferred revenue is being recognized as product is shipped to Merck based on the total amount of product expected to be shipped over the life of the agreement.

Research and Development Expenses:

Research and development (R&D) expenses decreased to $32.8 million in the third quarter of 2004 from $34.7 million for the same period of 2003, due primarily to a $4.1 million decrease in clinical trial expenses associated primarily with completion of the double-blind treatment portion of our AXOKINE phase 3 trial in 2003, the completion of other AXOKINE trials in the second quarter of 2004, and the completion of our IL-1 Trap phase 2 clinical trial in 2003. This decrease was partly offset by (i) a $1.3 million increase in payroll related expenses, resulting primarily from hiring additional research personnel, and (ii) a $0.9 million increase in other R&D expenses.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to $9.0 million in the third quarter of 2004 compared to $4.8 million in the same period in 2003, primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses increased to $4.2 million in the third quarter of 2004 from $3.6 million in the same period of 2003, due primarily to increases in professional fees principally related to our efforts to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and other accounting and professional services.

Other Income and Expense:

Investment income increased slightly to $1.4 million in the third quarter of 2004 from $1.3 million in the same period of 2003, due primarily to higher effective interest rates on investment securities. Interest expense is attributable principally to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum. Interest expense remained relatively unchanged at $3.0 million for both the third quarter of 2004 and 2003.

Nine Months Ended September 30, 2004 and 2003

Revenues:

Revenues in the nine months ended September 30, 2004 and 2003 consist of the following:

	(In millions)	
	2004	**2003**
Contract research & development revenue		
Aventis	$ 62.0	$ 2.6
Novartis	22.1	17.1
Procter & Gamble	8.1	7.9
Other	2.2	0.6
Total contract research & development revenue	94.4	28.2
Research progress payment	17.8	—
Contract manufacturing revenue	14.8	8.0
Total revenue	$127.0	$36.2

Our total revenue increased to $127.0 million in the first nine months of 2004 from $36.2 million for the same period in 2003 primarily from revenue related to our collaboration with Aventis on the VEGF Trap, which commenced in September 2003, and our collaboration with Novartis on the IL-1 Trap, which commenced in March 2003. Contract research and development revenue from our principal collaborators for the first nine months of 2004, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable, up-front payments. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period which we are obligated to perform services in accordance with SAB 104. In the first quarter of 2004, Novartis provided notice of its intention not to proceed with the joint development of the IL-1 Trap and the remaining balance of the March 2003 $27.0 million up-front payment from Novartis was recognized as contract research and development revenue.

For the nine months ended September 30, 2004
(In millions)

	Up-front Payment				
	Total Original Payment	Revenue Recognized	Deferred Revenue at September 30, 2004	Expense Reimbursement	Total Revenue Recognized
Aventis	$ 80.0	$ 8.2	$68.2	$53.8	$62.0
Novartis	27.0	22.1			22.1
Procter & Gamble				8.1	8.1
	$107.0	$30.3	$68.2	$61.9	$92.2

In the first nine months of 2003, we recognized $1.7 million in revenue related to the reimbursement of research and development expenses by Aventis and $0.9 million in revenue related to the $80.0 million up-front payment received from Aventis in September 2003. We also recognized $13.1 million in revenue related to the reimbursement of research and development expenses by Novartis and $4.0 million in revenue related to the $27.0 million, up-front payment received from Novartis in March 2003.

In March 2004, Novartis forgave all its outstanding loans, including accrued interest, to Regeneron totaling $17.8 million, based upon Regeneron's achieving a pre-defined development milestone, which was recognized as a research progress payment.

Contract manufacturing revenue increased to $14.8 million in the first nine months of 2004 from $8.0 million for the same period in 2003, principally from an increase in product shipments to Merck in 2004 compared to the same period in 2003. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in the first nine months of 2004 and 2003 was $3.0 million and $1.3 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. This deferred revenue is being recognized as product is shipped to Merck based on the total amount of product expected to be shipped over the life of the manufacturing agreement.

Research and Development Expenses:

Research and development (R&D) expenses decreased slightly to $101.3 million in the first nine months of 2004 from $102.8 million for the same period of 2003, due primarily to a $12.6 million decrease in clinical trial expenses associated primarily with the completion of the double-blind treatment portion of our AXOKINE phase 3 clinical trial in 2003, the completion of other AXOKINE trials in 2004, and the completion of our IL-1 Trap phase 2 clinical trial in 2003. This decrease was offset by (i) a $2.9 million increase in depreciation expense, primarily related to our expanded Rensselaer facility, (ii) a $3.4 million increase in payroll related expenses, resulting primarily from hiring additional research personnel, and (iii) a $4.8 million increase in other R&D expenses, primarily related to the VEGF Trap and IL-1 Trap.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to $11.7 million in the first nine months of 2004, compared to $5.8 million in the same period in 2003, primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses increased to $12.2 million in the first nine months of 2004 from $10.5 million in the same period of 2003, due primarily to professional fees principally related to our efforts to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and other accounting and professional services.

Other Income and Expense:

In the first quarter of 2004, Novartis notified us of its decision to forgo its right under the collaboration to jointly develop the IL-1 Trap and agreed to pay us $42.75 million to satisfy its obligation to fund development costs for the IL-1 Trap for the nine-month period following its notification and for the two months prior to that notice. The $42.75 million was included in other contract income in the first quarter of 2004.

Investment income remained relatively unchanged at $3.6 million for the first nine months of both 2004 and 2003. Interest expense is attributable principally to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum. Interest expense increased to $9.2 million in the first nine months of 2004 from $8.8 million in the same period of 2003 due, in part, to interest incurred in the first quarter of 2004 on loans from Novartis to fund our share of 2003 IL-1 Trap development costs. (These Novartis loans were forgiven in March 2004 as described above.)

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our agreements with Aventis, Novartis, Merck, Procter & Gamble, Serono, and other companies, and investment income.

Nine Months Ended September 30, 2004 and 2003

Cash (Used in) Provided by Operations:

At September 30, 2004, we had $361.2 million in cash, cash equivalents, marketable securities, and restricted marketable securities. Restricted marketable securities consisted of pledged U.S. government securities which were sufficient upon receipt of scheduled principal and interest payments to provide for the payment in full of the interest payments on the convertible senior subordinated notes through October, 2004. In the first nine months of 2004,

our net income was $38.9 million but we used $4.7 million of cash in operations. The difference between net income and cash usage was primarily due to the recognition of $39.9 million of non-cash deferred and research progress payment revenue related to the Novartis collaboration and $8.2 million of non-cash deferred revenue related to the Aventis collaboration. In the first nine months of 2003, our net loss was $88.1 million but we generated $22.3 million of cash in operations, principally due to the receipt of an $80.0 million non-refundable, up-front payment from Aventis in the third quarter of 2004 and a $27.0 million non-refundable, up-front payment from Novartis in the first quarter of 2003.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was $12.2 million in the first nine months of 2004, primarily because purchases of marketable securities exceeded cash proceeds from sales or maturities of marketable securities during this period. Net cash provided by investing activities was $92.6 million in the first nine months of 2003, as cash proceeds from sales or maturities of marketable securities substantially exceeded cash invested to purchase marketable securities. In addition, during the first nine months of 2004, payments for capital expenditures decreased $23.5 million compared to the same period in 2003, due primarily to the completion of the expansion of our Rensselaer, New York plant in 2003.

Cash Provided by Financing Activities:

Cash provided by financing activities decreased to $3.6 million in the first nine months of 2004 compared to $103.6 million in the same period in 2003. In connection with our collaboration agreements, we sold $45.0 million of newly issued unregistered shares of our Common Stock to Aventis in September 2003 and $48.0 million of newly issued unregistered shares of our Common Stock to Novartis in March 2003.

Aventis Agreement:

Under the collaboration agreement with Aventis, we and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a $25.0 million payment to us upon achievement of an early-stage clinical milestone. We expect to achieve this milestone within approximately the next six months. We may also receive up to $360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States.

We have agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap. Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by Aventis. We have the option to conduct additional pre-phase 3 studies at our own expense.

In 2004, we and Aventis increased research and development spending to expand the development of the VEGF Trap. Over the next 12 months, the broad based development

program is anticipated to include multiple studies to evaluate the VEGF Trap in single agent and in combination with other cancer treatments.

Also, under the terms of the Aventis collaboration agreement, if the collaboration becomes profitable, we will reimburse Aventis for 50 percent of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option.

Repurchase of Common Stock from Merck:

On August 19, 2004, we repurchased and subsequently retired 109,450 shares of our Common Stock held by Merck that were issued to Merck in August 2003 in connection with a patent license agreement. The shares were acquired for a purchase price of $0.9 million, based on the fair market value of the shares on August 19, 2004. We also made a cash payment of $0.6 million to Merck as required under the patent license agreement.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $4.7 million and $15.6 million for the first nine months of 2004 and 2003, respectively. During the remainder of 2004, we expect to incur approximately $1.5 million to $2.5 million in capital expenditures, related primarily to equipment for our expanded manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). We currently anticipate that approximately 50-55% of our expenditures for 2004 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, IL-1 Trap, IL-4/13 Trap, and AXOKINE; approximately 20-25% of our expenditures for 2004 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2004 will be used for capital expenditures and general corporate purposes, including working capital. In connection with our funding requirements, there has been no significant change in our contractual obligations for leases and long-term debt since December 31, 2003 except with regard to our loan payable to Novartis, which was forgiven in March 2004 (as described above). In addition in January 2004, we amended our Tarrytown, New York lease and exercised our option to extend the lease for certain parts of the leased space through December 2009. The effect of this extension was to increase our operating lease obligations to a total of $16.1 million for the years 2005 to 2007 and a total of $3.5 million for the years 2008 and 2009. The amended Tarrytown lease contains renewal options for certain parts of the leased space through December 2014.

The amount we need to fund operations 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 and development collaborations (including those with Aventis and Procter & Gamble). 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, 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. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements. Also, under the terms of the Aventis collaboration agreement, if the collaboration becomes profitable, we will reimburse Aventis for 50 percent of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option.

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.

We believe that our existing capital resources will enable us to meet operating needs through at least the end of 2006 and expect to end 2004 with a cash balance of $325 to $350 million. However, this is a forward-looking statement based on our current operating plan, and there may be a 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. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of September 30, 2004, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Future Impact of Recently Issued Accounting Standards

In April 2004, the Emerging Issues Task Force issued Statement No. 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share* (EITF 03-6). EITF 03-6 addresses a number of questions regarding the computation of earnings per share (EPS) by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares

dividends on its common stock. EITF 03-6 defines participation rights based solely on whether the holder would be entitled to receive any dividends if the entity declared them during the period and requires the use of the two-class method for computing basic EPS when participating convertible securities exist. In addition, EITF 03-6 expands the use of the two-class method to encompass other forms of participating securities and is effective for fiscal periods beginning after March 31, 2004. Since we have no participating securities, our adoption of EITF 03-6 did not have a material impact on our financial statements.

Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are included under other captions in this report and our Annual Report on Form 10-K and should be considered by our investors.

Risks Related to our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2004, we had a cumulative loss of $492.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products 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. We currently receive contract manufacturing revenue from our agreement with Merck and contract research and development revenue from our agreements with Procter & Gamble and Serono. All three of these agreements are scheduled to expire, unless extended by mutual agreement, before the end of 2005. We can provide no assurance that all or any of these agreements will be extended. Failure to extend those agreements may negatively impact our business, financial condition, or results of operations.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce, or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least the end of 2006; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional

financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction, or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition, or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our Common Stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payors and on our and our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human

clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, 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. A clinical trial may also fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. For example, the trials studying the maintenance of weight loss following short-term treatment regimens with AXOKINE did not enroll a sufficient number of patients to detect statistically significant differences between patients treated with AXOKINE and those taking placebo. These trials were designed before we had access to the data from the completed pivotal phase 3 AXOKINE trial, which demonstrated that the magnitude of the average difference in weight loss observed between all AXOKINE-treated subjects and those taking placebo was small.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of the product candidate, and our business, financial condition, and results of operations may be materially harmed.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These safety concerns may limit our ability to successfully develop the VEGF Trap.

Genentech and Eyetech are developing VEGF inhibiting molecules for certain diseases of the eye that will be delivered by direct administration to the eye. We plan to study the VEGF Trap for the potential treatment of certain diseases of the eye through intravitreal injections in the eye and are conducting trials of the VEGF Trap utilizing systemic administration through intravenous infusions or subcutaneous injections. Although we believe that there are potential clinical advantages to systemic administration over injections directly in the eye (including patient comfort and acceptance), there are unique potential risks to patients associated with the systemic blockade of VEGF by intravenous infusions or subcutaneous injections that could limit or end the VEGF Trap development program. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, include bleeding, hypertension, and proteinuria. Certain of these serious side effects and other serious side effects have been reported in our VEGF Trap studies. In addition, patients given infusions of any protein, including the VEGF Trap, may develop severe hypersensitivity reactions, referred to as infusion reactions. There may be additional complications or side effects that could harm the development of the VEGF Trap for either the treatment of cancer or diseases of the eye.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product 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 or clinical 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 completed. Approximately two-thirds of the subjects who received AXOKINE in the completed phase 3 study developed neutralizing antibodies. In addition, subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap in different patient populations and larger clinical trials, subjects given the VEGF Trap will develop antibodies to the product candidate.

A previous phase 3 study evaluating AXOKINE demonstrated modest average weight loss over a 12-month period. In addition, a completed phase 2 study evaluating the IL-1 Trap in patients with rheumatoid arthritis failed to achieve its primary endpoint.

In March 2003, we reported data from the 12-month treatment period of our initial phase 3 pivotal trial of AXOKINE. Although the phase 3 study met its primary endpoints and many individuals achieved a medically meaningful weight loss, the average weight loss was small and limited by the development of antibodies.

In October 2003, we reported results from the first phase 2 trial of our IL-1 Trap. While patients treated with the highest dose, 100 milligrams of the IL-1 Trap once a week, exhibited improvements in the primary endpoint of the trial, the proportion of ACR 20 responses versus

placebo, the results did not achieve statistical significance. We plan to conduct a phase 2b study of the IL-1 Trap in a larger patient population, testing higher doses than were tested in the previous phase 2 trial for a longer period of time. We plan to study higher doses of the IL-1 Trap through subcutaneous injections and intravenous delivery. However, higher doses may not lead to better results than were demonstrated in the previous phase 2 trial. In addition, safety or tolerability concerns may arise which limit our ability to deliver higher doses of the IL-1 Trap to patients. The dose levels that will be tested are substantially higher than the dose levels of other biological therapeutics currently approved for the treatment of rheumatoid arthritis. Either approach may affect the safety and/or tolerability of the IL-1 Trap, which may limit its commercial potential if the product candidate is ever approved for marketing and sale.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. We are currently involved in a product liability lawsuit brought by a subject who participated in a clinical trial of one of our drug candidates. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of its officers and directors in the United States District Court for the Southern District of New York. A consolidated amended class action complaint was filed in October 2003. The complaint, which purports to be brought on behalf of a class consisting of investors in our publicly traded securities between March 28, 2000 and March 30, 2003, alleges that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of

Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. No reserve for damages has been established because we do not believe that a loss is probable. However, if the outcome of the litigation is adverse to us, we could be subject to significant liability, which could exceed our insurance coverage.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Risks Related to our Dependence on Third Parties

On February 27, 2004, Novartis provided notice to us that they would not participate in the continued development and commercialization of the IL-1 Trap under our collaboration agreement. This may harm our ability to develop and commercialize the IL-1 Trap.

We relied heavily on Novartis to provide their expertise, resources, funding, manufacturing capacity, clinical expertise, and commercial infrastructure to support the IL-1 Trap program. Novartis' decision to withdraw from participating in the development and commercialization of the IL-1 Trap may delay or disrupt the IL-1 Trap program. We do not have the resources and skills to replace those of Novartis, which could result in significant delays in the development and potential commercialization of the IL-1 Trap. In addition, we will have to fund the development and commercialization of the IL-1 Trap without Novartis' long-term commitment, which will require substantially greater expenditures on our part.

If our collaboration with Aventis for the VEGF Trap is terminated, our ability to develop and commercialize the VEGF Trap in the time expected, or at all, and our business operations would be harmed.

We rely heavily on Aventis to assist with the development of the VEGF Trap. If the VEGF Trap program continues, we will rely on Aventis to assist with providing commercial manufacturing capacity, enrolling and monitoring clinical trials, obtaining regulatory approval, particularly outside the United States, and providing sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if Aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap will be significantly adversely affected. Aventis has the right to terminate its collaboration agreement with us at any time. If Aventis

were to terminate its collaboration agreement with us, we might not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the Aventis collaboration agreement would create new and additional risks to the successful development of the VEGF Trap.

Sanofi-Synthelabo recently acquired Aventis, forming the sanofi-aventis Group. At present, it is unclear what impact, if any, this business combination will have on the VEGF Trap collaboration, including the possibility of a termination of the collaboration agreement and a delay in, or disruption to, the VEGF Trap development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including Aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we would experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development and, following approval, in commercial quantities, in compliance with regulatory requirements and at competitive costs. If we or any of our product collaborators or third-party manufacturers, fillers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient

material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We maintain an 8,000 square foot manufacturing facility in Tarrytown, New York and have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, we produce an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. We also use our facilities to produce API for our own clinical and preclinical candidates. If we no longer use our facilities to manufacture the Merck intermediate or clinical candidates are discontinued, we would have to absorb overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our operating results.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute these sources to comply with

European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing, or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of the agreement, we currently rely on Aventis for sales, marketing, and distribution of the VEGF Trap, should it be approved in the future for marketing by regulatory authorities. We will have to rely on a third party or devote significant resources to develop our own sales, marketing and distribution capabilities for our other product candidates and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including VEGF Trap, IL-1 Trap, IL-4/13 Trap and AXOKINE, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates. For example, we are in the process of developing formulations that would allow delivery of higher doses of the IL-1 Trap to test in clinical trials. The dose levels that will be tested are substantially higher than the dose levels of other biological therapeutics currently approved for treatment of rheumatoid arthritis. Separate new formulations will be used for subcutaneous and intravenous administration of the higher dose therapeutic. If we are unable to develop or manufacture such a higher dose formulation that can be produced in a cost-effective manner, potential future IL-1 Trap sales and profitability may be limited.

Even if our product candidates are ever approved, their commercial success is highly uncertain because our competitors may get to the marketplace before we do with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve product commercialization before our products are approved for marketing and sale. Genentech has an approved VEGF antagonist on the market and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. The marketing approval for Genentech's VEGF antagonist, Avastin™, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap.

The markets for both rheumatoid arthritis and asthma are both very competitive. Several highly successful medicines are available for these diseases. Examples include the TNF-antagonists Enbrel® (a registered trademark of Amgen), Remicade® (a registered trademark of Centocor), and Humira® (a registered trademark of Abbott) for rheumatoid arthritis, and the leukotriene-modifier Singulair® (a registered trademark of Merck), as well as various inexpensive corticosteroid medicines for asthma. The availability of highly effective FDA approved TNF-antagonists makes it more difficult to successfully develop the IL-1 Trap for the treatment of rheumatoid arthritis, since it will be difficult to enroll patients with rheumatoid arthritis to participate in clinical trials of the IL-1 Trap. This may delay or impair our ability to successfully develop the drug candidate. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections. In addition, there are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap.

There is also substantial competition in the discovery and development of treatments for obesity, as well as established, cost-effective, and emerging surgical, prescription, and over-the-counter treatments for the disease that may offer competitive advantages over AXOKINE. AXOKINE is available only in injectable form, while the currently available marketed medicines for the treatment of obesity, and a late-stage product candidate in development by sanofi-aventis Group, are delivered in pill form, which is generally favored over injectable medicines. Therefore, even if AXOKINE is approved for sale, the fact that it must be delivered by injection may severely limit its market acceptance among patients and physicians.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payors.

Sales of biopharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payors, the market for any biopharmaceutical product will be limited. These third-party payors increasingly challenge the price and examining

the cost-effectiveness of products and services. Significant uncertainty exists as to the reimbursement status of any new therapeutic, particularly if there exist lower-cost standards of care. Third-party payors may not reimburse sales of our products, which would harm our business.

Risks Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of Roy Vagelos, M.D., the Chairman of our Board of Directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be expensive and time consuming.

We may be restricted in our development and/or commercialization activities by third party patents.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege to have blocking patents to our Trap products in clinical development, either because they claim to hold proprietary rights to fusion proteins or proprietary rights to components of the Trap or the way it is manufactured. We are aware of certain United States and foreign patents relating to particular IL-4 and IL-13 receptors. Our IL-4/13 Trap includes portions of the IL-4 and IL-13 receptors. In addition, we are aware of a broad patent held by Genentech relating to proteins fused to certain immunoglobulin domains. Our Trap product candidates include proteins fused to immunoglobulin domains. Although we do not believe that we are infringing valid and enforceable third party patents, the holders of these patents may sue us for infringement and a court may find that we are infringing one or more validly issued patents, which may materially harm our business.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

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

Risks Related to our Common Stock

Our stock price may be extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price.

A number of our shareholders own a substantial amount of our Common Stock. If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, the market price of our Common Stock could fall. Sales by our significant shareholders, including Aventis, and Novartis, also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deemed appropriate.

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. We estimate that a one percent change in interest rates would have resulted in an approximately $1.8 million and $1.4 million change in the fair market value of our investment portfolio at September 30, 2004 and December 31, 2003, respectively. The increase is due primarily to the longer duration of our investment portfolio as of September 30, 2004 in comparison to December 31, 2003.

Item 4. Controls and Procedures

We conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The evaluation was conducted under the supervision and with the participation of Leonard S. Schleifer, our President and Chief Executive Officer, and Murray A. Goldberg, our Chief Financial Officer. Based upon this evaluation, each of Dr. Schleifer and Mr. Goldberg concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our filings under the Securities Exchange Act of 1934. There has been no significant change in our internal controls over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In order to achieve compliance with Section 404 of the Sarbanes-Oxley Act of 2002, we have been engaged in a process to document and evaluate our internal control over financial reporting. In this regard, under the review and approval of the Audit Committee, management has dedicated internal resources and engaged outside consultants to adopt a work plan to (i) assess the adequacy of our internal control over financial reporting, (ii) take steps to improve control

processes, where appropriate, and (iii) validate through testing that controls are functioning as documented. During the third quarter of 2004, we implemented and tested many new procedures and controls. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our Common Stock.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing, we intend to continue to examine and refine our disclosure controls and procedures and monitor ongoing developments in this area.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of its officers and directors in the United States District Court for the Southern District of New York. A consolidated amended class action complaint was filed in October 2003. The complaint, which purport to be brought on behalf of a class consisting of investors in our publicly traded securities between March 28, 2000 and March 30, 2003, alleges that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. We believe that the lawsuit is without merit and in December 2003, we filed a motion to dismiss the lawsuit. Because we do not believe that a loss is probable, no legal reserve has been established.

From time to time we are a party to other legal proceedings in the course of our business. We do not expect any other legal proceedings to have a material adverse effect on our business or financial condition.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On August 19, 2004, we repurchased and subsequently retired 109,450 shares of our Common Stock held by Merck that were issued to Merck in August 2003 in connection with a patent license agreement. The shares were acquired for a purchase price of $0.9 million (or $8.12 per share) based on the fair market value of the shares on August 19, 2004.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit Number	Description
3.1	(a) - Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., dated as of June 21, 1991.
3.2	(b) - Certificate of Amendment of the Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., dated as of October 18, 1996.
3.3	(c) - Certificate of Amendment of the Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., dated as of December 17, 2001.
3.4	(d) - By-Laws of the Company, currently in effect (amended as of January 22, 1995).

Exhibit Number	Description
31	- Certification of CEO and CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 1991, filed August 13, 1991.

(b) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1996, filed November 5, 1996.

(c) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2001, filed March 22, 2002.

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1994, filed March 30, 1995.

(b) Reports

Form 8-K, filed October 28, 2004: On October 28, 2004, we issued a press release announcing our third quarter 2004 financial and operating results.

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 8, 2004

By: /s/ Murray A. Goldberg

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

Exhibit 31

Certification of CEO and CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

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 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 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-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's

auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2004

By: /s/ Leonard S. Schleifer

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

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 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 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-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2004

By: /s/ Murray A. Goldberg

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

Exhibit 32

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, 2004 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 results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
November 8, 2004

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
November 8, 2004

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.