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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)
☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2005

OR

o 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 ☑ No o

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

Yes o No ☑

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of April 30, 2005:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,358,373
Common Stock, $0.001 par value	53,763,078

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March 31, 2005

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT MARCH 31, 2005 AND DECEMBER 31, 2004 (Unaudited)
(In thousands, except share data)

	March 31, 2005	December 31, 2004
ASSETS		
Current assets		
Cash and cash equivalents	$ 147,816	$ 95,229
Marketable securities	206,090	200,753
Accounts receivable	10,371	43,102
Prepaid expenses and other current assets	2,490	1,642
Inventory	3,087	3,229
Total current assets	369,854	343,955
Marketable securities	26,622	52,930
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	69,055	71,239
Other assets	4,761	4,984
Total assets	$ 470,292	$ 473,108
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 17,468	$ 18,872
Deferred revenue, current portion	12,463	15,267
Total current liabilities	29,931	34,139
Deferred revenue	54,577	56,426
Notes payable	200,000	200,000
Total liabilities	284,508	290,565
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 2005 and 2004	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized;		
53,763,234 shares issued and outstanding in 2005		
53,502,004 shares issued and outstanding in 2004	54	54
Additional paid-in capital	682,578	675,389
Unearned compensation	(1,783)	(2,299)
Accumulated deficit	(493,957)	(489,834)
Accumulated other comprehensive loss	(1,110)	(769)
Total stockholders' equity	185,784	182,543
Total liabilities and stockholders' equity	$ 470,292	$ 473,108

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 March 31,	
	2005	**2004**
Revenues		
Contract research and development	$ 13,502	$ 41,610
Research progress payments		17,770
Contract manufacturing	2,707	2,610
	16,209	61,990
Expenses		
Research and development	35,912	32,181
Contract manufacturing	2,491	2,225
General and administrative	6,146	3,790
	44,549	38,196
Income (loss) from operations	(28,340)	23,794
Other income (expense)		
Other contract income	25,000	42,750
Investment income	2,230	1,124
Interest expense	(3,013)	(3,136)
	24,217	40,738
Net income (loss)	$ (4,123)	$ 64,532
Net income (loss) per share:		
Basic	$ (0.07)	$ 1.17
Diluted	$ (0.07)	$ 1.06
Weighted average shares outstanding:		
Basic	55,815	55,283
Diluted	55,815	63,625

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2005
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount						
Balance, December 31, 2004	2,358	$ 2	53,502	$ 54	$ 675,389	$ (2,299)	$ (489,834)	$ (769)	$ 182,543	
Issuance of Common Stock in connection with exercise of stock options			172		1,030				1,030	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			90		632				632	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(1)		(14)	14				
Stock-based compensation expense					5,541	502			6,043	
Net loss							(4,123)		(4,123)	$ (4,123)
Change in net unrealized loss on marketable securities								(341)	(341)	(341)
Balance, March 31, 2005	2,358	$ 2	53,763	$ 54	$ 682,578	$ (1,783)	$ (493,957)	$ (1,110)	$ 185,784	$ (4,464)

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

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

	Three months ended March 31,	
	2005	**2004**
Cash flows from operating activities		
Net income (loss)	$ (4,123)	$ 64,532
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities		
Depreciation and amortization	3,858	3,773
Non-cash compensation expense	5,881	671
Non-cash expense related to a license agreement		13
Forgiveness of loan payable to Novartis Pharma AG, inclusive of accrued interest		(17,770)
Changes in assets and liabilities		
Decrease (increase) in accounts receivable	32,731	(44,353)
Increase in prepaid expenses and other assets	(40)	(943)
Decrease in inventory	527	188
Decrease in deferred revenue	(4,653)	(25,994)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(1,049)	1,301
Total adjustments	37,255	(83,114)
Net cash provided by (used in) operating activities	33,132	(18,582)
Cash flows from investing activities		
Purchases of marketable securities	(35,601)	
Purchases of restricted marketable securities		(5,500)
Sales or maturities of marketable securities	55,385	74,216
Maturities of restricted marketable securities		5,500
Capital expenditures	(1,359)	(985)
Net cash provided by investing activities	18,425	73,231
Cash flows from financing activities		
Net proceeds from the issuance of stock	1,030	274
Borrowings under loan payable		3,827
Net cash provided by financing activities	1,030	4,101
Net increase in cash and cash equivalents	52,587	58,750
Cash and cash equivalents at beginning of period	95,229	97,477
Cash and cash equivalents at end of period	$ 147,816	$ 156,227

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

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(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 accounting principles generally accepted in the United States of America. 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, 2004 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. 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, 2004.

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 March 31, 2005, 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 (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months Ended March 31, 2005	2004
Income (loss) (Numerator):		
Net income (loss) for basic per share calculations	$ (4,123)	$ 64,532
Adjustment for interest expense on convertible notes	—	2,750
Adjusted net income (loss) for diluted per share calculations	$ (4,123)	$ 67,282
Shares, in thousands (Denominator):		
Weighted-average shares for basic per share calculations	55,815	55,283
Effect of stock options		1,668
Effect of restricted stock awards		63
Effect of convertible notes		6,611
Adjusted weighted-average shares for diluted per share calculations	55,815	63,625
Basic net income (loss) per share	$ (0.07)	$ 1.17
Diluted net income (loss) per share	$ (0.07)	$ 1.06

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2005 and 2004 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended March 31, 2005	2004
Stock Options:		
Weighted average number, in thousands	13,476	7,423
Weighted average exercise price	$ 14.73	$ 27.98
Restricted Stock:		
Weighted average number, in thousands	213	
Convertible Debt:		
Weighted average number, in thousands	6,611	
Conversion price	$ 30.25	

3. Stock-based Employee Compensation

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards (“SFAS”) No. 123, *Accounting for Stock-Based*

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

Compensation, using the modified prospective method as described in SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. As a result, the Company has begun recognizing expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005, (including replacement options granted under the Company's stock option exchange program which concluded on January 5, 2005 (see Note 11)) and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, the Company accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period results have not been restated. In the first quarter of 2005, non-cash stock-based employee compensation expense related to stock options awards ("Stock Option Expense") totaled $5,541, of which $5,379 was recognized in operating expenses and $162 was capitalized in inventory. In the first quarter of 2004, had the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS No. 123, Stock Option Expense would have totaled $8,925 and the effect on the Company's net income and net income per share would have been as follows:

	Three months ended March 31, 2004
Net income, as reported	$ 64,532
Add: Stock-based employee compensation expense included in reported net income	671
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(9,596)
Pro forma net income, basic	$ 55,607
Pro forma net income, diluted	$ 58,357
Basic net income per share amounts:	
As reported	$ 1.17
Pro forma	$ 1.01
Diluted net income per share amounts:	
As reported	$ 1.06
Pro forma	$ 0.92

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

The fair value of each option granted from the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan") during the three months ended March 31, 2005 and 2004 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are based, in part, on the Company's limited historical exercise experience with option grants with similar exercise prices and, in part, on comparisons to expected lives reported by peers in the biotechnology industry. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended March 31, 2005 and 2004 was $5.86 and $11.00 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

	Three months ended March 31,	
	2005	2004
Expected volatility	75%	80%
Expected lives from grant date	6.2 years	7.3 years
Dividend yield	0%	0%
Risk-free interest rate	3.96%	3.73%

Under the 2000 Incentive Plan, the Company also awards shares of restricted stock. 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 March 31, 2005 and 2004, the Company recognized compensation expense related to restricted stock awards of $502 and $671, respectively.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2005 and December 31, 2004 are $827 and $550, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2004 and December 31, 2003 are $452 and $752, respectively, of accrued capital expenditures.

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

Included in accounts payable and accrued expenses at December 31, 2004 and 2003 are $632 and $917, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2005 and 2004, the Company contributed 90,385 and 64,333 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2005 and December 31, 2004 are $1,760 and $2,601, respectively, of accrued interest income. Included in marketable securities at March 31, 2004 and December 31, 2003 are $1,023 and $878, respectively, of accrued interest income.

5. Marketable Securities

The Company has revised the classification of its investments in auction rate securities from cash and cash equivalents to short-term investments on its balance sheet at December 31, 2004. Auction rate securities are securities that have stated maturities beyond three months, but are priced and traded as short-term investments due to the liquidity provided through the auction mechanism that generally resets interest rates every 28 or 35 days. The change in classification resulted in a $6,005 decrease in cash and cash equivalents and corresponding increase in short-term marketable securities at December 31, 2004. The Company held no auction rate securities at March 31, 2005. In addition, the Company revised its statement of cash flows for the three months ended March 31, 2004 to reflect the purchases and sales of these securities as investing activities rather than as a component of cash and cash equivalents, resulting in a $3,001 increase in cash flows from investing activities. This change in classification had no impact on the Company's previously reported current assets, net income (loss), or cash flows from operations.

6. Accounts Receivable

Accounts receivable as of March 31, 2005 and December 31, 2004 consist of the following:

	March 31, 2005	December 31, 2004
Receivable from the sanofi-aventis Group	$ 7,581	$ 39,362
Receivable from The Procter & Gamble Company	2,690	2,345
Receivable from Merck & Co., Inc.	60	1,315
Other	40	80
	$ 10,371	$ 43,102

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

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement.

Inventories as of March 31, 2005 and December 31, 2004 consist of the following:

	March 31, 2005	December 31, 2004
Raw materials	$ 339	$ 310
Work-in-process	266(1)	692(3)
Finished products	2,482(2)	2,227
	$ 3,087	$ 3,229

(1) Net of reserves of $490.
(2) Net of reserves of $427.
(3) Net of reserves of $256.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2005 and December 31, 2004 consist of the following:

	March 31, 2005	December 31, 2004
Accounts payable	$ 3,071	$ 4,407
Accrued payroll and related costs	5,596	7,972
Accrued clinical trial expense	1,607	2,083
Accrued expenses, other	2,152	2,118
Interest payable on convertible notes	5,042	2,292
	$ 17,468	$ 18,872

9. 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 (loss) on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. For the three months ended March 31, 2005 and 2004, the components of comprehensive income (loss) are:

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

	Three months ended March 31,	
	2005	2004
Net income (loss)	$ (4,123)	$ 64,532
Change in net unrealized gain (loss) on marketable securities	(341)	69
Total comprehensive income (loss)	$ (4,464)	$ 64,601

10. Research and Development Agreement – The sanofi-aventis Group

In September 2003, the Company entered into a collaboration agreement (the "s-a Agreement") with Aventis Pharmaceuticals, Inc., now a member of the sanofi-aventis Group, to jointly develop and commercialize the Company's Vascular Endothelial Growth Factor ("VEGF") Trap. In connection with this agreement, Aventis Pharmaceuticals made a non-refundable up-front payment of $80.0 million and purchased $45.0 million of newly issued, unregistered shares of the Company's Common Stock.

In January 2005, the Company and sanofi-aventis amended the s-a Agreement to exclude rights to develop and commercialize the VEGF Trap for eye diseases through local delivery systems, and these VEGF Trap product rights reverted to Regeneron. In connection with this amendment, sanofi-aventis made a one-time $25.0 million payment to Regeneron in January 2005. Under the s-a Agreement, as amended, Regeneron and sanofi-aventis will share co-promotion rights for and profits on sales, if any, from the VEGF Trap, for disease indications included in the companies' collaboration.

Under the s-a Agreement, as amended, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will reimburse sanofi-aventis for 50% of the VEGF Trap development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to the collaboration agreement, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits, or at a faster rate at Regeneron's option. In addition, if the first commercial sale of a VEGF Trap product for diseases of the eye through local delivery systems predates the first commercial sale of a VEGF Trap product under the collaboration, Regeneron will begin reimbursing sanofi-aventis for up to $7.5 million of VEGF Trap development expenses commencing two years after such initial commercialization outside the collaboration in accordance with a defined formula, until the first commercial VEGF Trap sale under the collaboration occurs.

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

11. Stock Option Exchange Program

In December 2004, the Company's shareholders approved a stock option exchange program. Under the program, Company regular employees who worked an average of 20 hours per week, other than the Company's chairman and the Company's president and chief executive officer, were provided the opportunity to make a one-time election to surrender options granted under the Company's Long-Term Incentive Plans that had an exercise price per share of at least $18.00 and exchange them for replacement options granted under the 2000 Incentive Plan in accordance with the following exchange ratios:

Exercise Price of Eligible Options	Exchange Ratio (Number of Eligible Options Surrendered and Cancelled for Each Replacement Option)
$18.00 to $28.00	1.50
$28.01 to $37.00	2.00
$37.01 and up	3.00

Participation in the stock option exchange program was voluntary, and non-employee directors, consultants, former employees, and retirees were not eligible to participate. The participation deadline for the program was January 5, 2005. Eligible employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and on January 5, 2005, the Company issued replacement options with respect to a total of 1,977,840 underlying shares of Common Stock at an exercise price of $8.50 per share.

12. 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 & Co., Inc. pediatric vaccine under a long-term manufacturing agreement.

The table below presents information about reported segments for the three months ended March 31, 2005 and 2004.

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

	Three months ended March 31, 2005			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 13,502	$ 2,707	—	$ 16,209
Depreciation and amortization	3,597	-(1)	$ 261	3,858
Other contract income	25,000	—	—	25,000
Interest expense	—	—	3,013	3,013
Net (loss) income	(3,556)	216	(783)(2)	(4,123)
Capital expenditures	1,637	—	—	1,637
Total assets	77,527	4,986	387,779(3)	470,292

	Three months ended March 31, 2004			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 59,380	$ 2,610	—	$ 61,990
Depreciation and amortization	3,512	-(1)	$ 261	3,773
Other contract income	42,750	—	—	42,750
Interest expense	126	—	3,010	3,136
Net (loss) income	66,033	385	(1,886)(2)	64,532
Capital expenditures	685	—	—	685
Total assets	133,931	12,665	359,582(3)	506,178

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.
(2) Represents investment income, net of interest expense related primarily 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.

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, a product then being developed by the Company for the treatment of obesity, 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 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 March 31, 2005 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 December 2004, the FASB issued Statement of Financial Accounting Standards No. 123R ("SFAS No. 123R"), *Share-Based Payment*. SFAS No. 123R is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS No. 123R establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS No. 123R is effective for fiscal years beginning after June 15, 2005. The Company will be required to adopt SFAS No. 123R effective for the fiscal year beginning January 1, 2006, and intends to do so using the modified prospective method. Under the modified prospective method, compensation cost is recognized beginning with the effective date based on (a) the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. Although the impact of adopting SFAS No. 123R has not yet been quantified, management believes that the future adoption of this standard may have a material 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 future events and 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, 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 pipeline of product candidates that we believe has 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 March 31, 2005:

- **VEGF TRAP — Oncology:** 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 milligrams per kilogram of body weight (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.

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. Preliminary results of this trial will be presented at the annual meeting of ASCO in May 2005.

We and the sanofi-aventis Group plan to initiate multiple clinical studies in 2005 to evaluate the VEGF Trap as a single-agent and in combination with other therapies in various cancer indications. 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, we and sanofi–aventis plan to initiate a clinical trial in that indication in 2005.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (now a member of the sanofi-aventis Group) to jointly develop and commercialize the VEGF Trap throughout the world with the exception of Japan, where product rights remain with us. Under the collaboration agreement, as amended in January 2005, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap for disease indications included in our collaboration. In December 2004, we earned a $25.0 million payment from sanofi-aventis, which was received in January 2005, upon the achievement of an early stage clinical milestone. 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

Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the

collaboration becomes profitable, we will reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profit, or at a faster rate at our option.

- **VEGF TRAP – Eye Diseases**: VEGF both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in diabetic retinopathy, diabetic macular edema, and age-related macular degeneration, and is believed to be involved in other medical problems affecting the eyes. In January 2005, we and sanofi-aventis amended our collaboration agreement to exclude rights to develop and commercialize the VEGF Trap for eye diseases through local delivery systems. We now have the exclusive right to develop and commercialize the VEGF Trap for eye diseases through local administration to the eye and plan to initiate a clinical trial of the VEGF Trap delivered through intravitreal injection in mid-2005. While use of the VEGF Trap for eye diseases using systemic delivery remains part of our collaboration with sanofi-aventis, we and sanofi-aventis do not currently intend to pursue further clinical development using systemic delivery of VEGF Trap for eye diseases.

  Two phase 1 clinical trials of the VEGF Trap delivered systemically in patients with the neovascular form of age-related macular degeneration (wet AMD) and diabetic macular edema (DME) were completed in 2004. The results of the study of the VEGF Trap in 25 patients with advanced wet AMD were discussed at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) in May 2005. The trial successfully met its pre-specified efficacy endpoint as preliminary results from the trial indicated that the VEGF Trap demonstrated a statistically significant decrease in excess retinal thickness in treated patients, which increased in both magnitude and duration with higher doses. The trial results also showed that the VEGF Trap caused a dose-dependent increase in blood pressure (hypertension), which appears to be a “class-effect” of systemically administered anti-VEGF agents. We plan to initiate a phase 1 trial of the VEGF Trap in mid-2005 in advanced wet AMD patients using direct injections into the eye.

- **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 may play an important role in a number of rheumatological and other diseases and disorders, including diseases associated with inflammation in blood vessels.

  In October 2003, we announced that the IL-1 Trap demonstrated evidence of clinical activity and safety in patients with rheumatoid arthritis 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. Patients in this trial experienced statistically significant reductions in C-reactive protein (CRP) levels, and the improvements in CRP levels demonstrated a clear dose response to the IL-1 Trap. The IL-1 Trap was generally well tolerated and no serious drug-related adverse events were reported.

  We are nearing completion of safety and tolerability studies in healthy individuals being treated with higher doses of the IL-1 Trap. We plan to further evaluate the safety and efficacy of the IL-1 Trap in rheumatoid arthritis in a double blind, placebo-controlled, multi-center trial. This trial will be conducted in a larger patient population, testing higher doses of IL-1 Trap for a longer period of time than the phase 2 trial completed in 2003. We expect to evaluate doses of 160 milligrams and 320 milligrams of IL-1 Trap delivered

subcutaneously once a week. Additional trials of the IL-1 Trap will be required to support an application seeking approval to market the IL-1 Trap in rheumatoid arthritis.

In the fourth quarter of 2004, we initiated a pilot study of the IL-1 Trap in patients with *CIAS*1-Associated Periodic Syndrome (CAPS), a spectrum of rare diseases associated with mutations in the *CIAS*-1 gene. IL-1 appears to play a significant role in these diseases. In December 2004, the FDA granted orphan drug status to the IL-1 Trap for the treatment of these diseases. We expect to commence an additional trial for this indication in 2005.

We believe blocking IL-1 could be useful in a number of potential indications where inflammation plays a role. Examples include such indications as osteoarthritis, certain rare genetic diseases, Still's disease and cardiovascular diseases. In April 2005, we initiated a proof-of-concept study of the IL-1 Trap in osteoarthritis and later in 2005, we plan to initiate several other proof-of-concept studies to identify indications where the IL-1 Trap demonstrates evidence of efficacy and safety.

Under the terms of our March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development, and Novartis has the right to elect to collaborate in the development and commercialization of our second generation IL-1 Trap, which is in pre-clinical development.

- **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. Based on preclinical data, IL-4 and IL-13 are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. At a scientific conference during the second quarter of 2004, we presented the results of a placebo-controlled, double-blind, dose escalation phase 1 trial of the IL-4/13 Trap using subcutaneous injections in adult subjects with mild to moderate asthma. The IL-4/13 Trap was generally safe and well tolerated at the doses tested. We plan to initiate a phase 2 trial in the second half of 2005 to evaluate the safety and potential efficacy of the IL-4/13 Trap in asthma or allergy indications.

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 U.S. Food and Drug Administration (or 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 March 31, 2005, we had a cumulative loss of $494.0 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, and IL-4/13 Trap; 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 clinical programs, key first quarter 2005 events and plans for the remainder of 2005 are as follows:

Product Candidate	2005 Events to Date	Additional 2005 Plans
VEGF Trap — Oncology	• Sanofi-aventis reaffirmed their commitment to the collaborative development of the VEGF Trap in oncology	• Commence additional single-agent and combination trials in cancer
VEGF Trap — Eye Diseases	• Continued preclinical activities for intraocular injection of VEGF Trap	• Commence clinical trial in eye disease utilizing local delivery by intravitreal injections
IL-1 Trap	• Successfully completed safety and tolerability studies of IL-1 Trap at higher doses • Commenced clinical trial in osteoarthritis • Successfully completed initial treatment phase of proof-of-concept study in *CIAS*1-Associated Periodic Syndrome (CAPS)	• Commence clinical trial in rheumatoid arthritis • Commence exploratory proof-of-concept trials in other indications • Complete CAPS proof-of-concept study and commence additional trial in this indication • Evaluate IL-1 Trap in other inflammatory conditions
IL-4/13 Trap		• Commence clinical trial in asthma or allergy indication

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting

Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS No. 148, *Accounting for Stock-Based Compensation— Transition and Disclosure*. As a result, we have begun recognizing expense in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards. Under the modified prospective method, we recognize compensation expense for (a) all share based payments granted on or after January 1, 2005, (including replacement options granted under our stock option exchange program which concluded on January 5, 2005) and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25), and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results have not been restated. In the first quarter of 2005, non-cash stock-based employee compensation expense related to stock options awards ("Stock Option Expense") totaled $5.6 million, of which $5.4 million was recognized in operating expenses and $0.2 million was capitalized in inventory.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted from the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are based, in part, on our limited historical exercise experience with option grants with similar exercise prices and, in part, on comparisons to expected lives reported by peers in the biotechnology industry. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average values of the assumptions we used in computing the fair value of option grants during the first quarter of 2005:

Expected volatility	75%
Expected lives	6.2 years
Dividend yield	0%
Risk-free interest rate	3.96%

Changes in any of these estimates may materially affect the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended March 31, 2005 and 2004

Non-GAAP Financial Measures:

As described above, effective January 1, 2005, Regeneron began recognizing Stock Option Expense in accordance with SFAS No. 123 in each of the categories of expense in our Statement of Operations. Prior to the adoption of SFAS No. 123, Stock Option Expense was not reflected in operating expenses and prior period operating results have not been restated.

The discussion of our results of operations for the three months ended March 31, 2005 and 2004 includes certain financial measures that are calculated in a manner different from generally accepted accounting principles (GAAP) and are considered non-GAAP financial measures under United States Securities and Exchange Commission (SEC) rules. These non-GAAP financial measures for the three months ended March 31, 2005 are: (1) pro forma net income and pro forma net income per share (basic and diluted), exclusive of Stock Option Expense and (2) research and development expenses, general and administrative expenses, and contract manufacturing expenses, all exclusive of Stock Option Expense. Our management does not intend that the presentation of non-GAAP financial measures be considered in isolation or as a substitute for results prepared in accordance with GAAP.

Our management believes that the non-GAAP financial measures described above present helpful information to investors and other users of Regeneron's financial statements by providing greater transparency about the nature of and trends in our operating expenses and net income and a more useful basis for comparing our operating results in the first quarters of 2005 and 2004. In addition, Regeneron's management uses non-GAAP financial measures which exclude Stock Option Expense internally for operating, budgeting, and financial planning purposes. In our discussion below we have included tables which provide a reconciliation of the differences between these non-GAAP financial measures and the most directly comparable financial measures calculated and presented in accordance with GAAP.

Net Income (Loss):

Regeneron reported a net loss of $4.1 million, or $0.07 per share (basic and diluted) for the first quarter of 2005 compared with net income of $64.5 million, or $1.17 per basic share and $1.06 per diluted share, for the first quarter of 2004. Excluding Stock Option Expense, Regeneron had pro forma net income of $1.3 million, or $0.02 per share (basic and diluted), in the first quarter of 2005 as follows:

For the three months ended March 31, 2005 *(in millions, except per share data)*	**Net Income (Loss)**	**Net Income (Loss) per Share - Basic and Diluted**
Net loss, as reported	$ (4.1)	$ (0.07)
Add: Stock Option Expense	5.4	0.09
Pro forma net income, exclusive of Stock Option Expense	$ 1.3	$ 0.02

Revenues:

Revenues in the three months ended March 31, 2005 and 2004 consist of the following:

	(In millions)	
	2005	2004
Contract research & development revenue		
The sanofi-aventis Group	$ 9.8	$ 16.4
Novartis Pharma AG	—	22.1
The Procter & Gamble Company	3.1	2.7
Other	0.6	0.4
Total contract research & development revenue	13.5	41.6
Research progress payment	—	17.8
Contract manufacturing revenue	2.7	2.6
Total revenue	$ 16.2	$ 62.0

Our total revenue decreased to $16.2 million in the first quarter of 2005 from $62.0 million in the same period of 2004 due primarily to lower revenues related to our collaboration with sanofi-aventis on the VEGF Trap and our prior collaboration with Novartis on the IL-1 Trap. Collaboration revenue earned from sanofi-aventis and Novartis is comprised of contract research and development revenue and research progress payments. Contract research and development revenue, 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 over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

Sanofi-aventis and Novartis contract research & development revenues for the three months ended March 31, 2005 and 2004 were as follows:

		Up-front Payment to Regeneron			
For the three months ended March 31, 2005 *(in millions)*	**2005 Regeneron Expense Reimbursement**	**Total Payment**	**Amount Recognized in 2005**	**Deferred Revenue at March 31, 2005**	**Total Revenue Recognized in 2005**
Sanofi-aventis	$ 7.4	$ 80.0	$ 2.4	$ 63.5	$ 9.8

		Up-front Payment to Regeneron			
For the three months ended March 31, 2004 *(in millions)*	**2004 Regeneron Expense Reimbursement**	**Total Payment**	**Amount Recognized in 2004**	**Deferred Revenue at March 31, 2004**	**Total Revenue Recognized in 2004**
Sanofi-aventis	$ 13.7	$ 80.0	$ 2.7	$ 73.6	$ 16.4
Novartis	—	27.0	22.1	—	22.1
Total	$ 13.7	$ 107.0	$ 24.8	$ 73.6	$ 38.5

Sanofi-aventis reimbursement of Regeneron VEGF Trap expenses decreased in the first quarter of 2005 from the same period in 2004, primarily due to lower costs in 2005 related to our manufacture of VEGF Trap clinical supplies. 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 $27.0 million up-front payment received from Novartis in March 2003 was recognized as contract research and development revenue. We do not expect future contract research and development revenue from Novartis.

In March 2004, Novartis forgave all of its outstanding loans, including interest, to us totaling $17.8 million, based upon our achievement of a pre-defined IL-1 Trap development milestone, which was recognized as a research progress payment.

Contract manufacturing revenue relates to our long-term agreement with Merck to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue was $2.7 million in the first quarter of 2005 and $2.6 million in the same period of 2004 as we shipped similar quantities of product to Merck each quarter. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in the first three months of 2005 and 2004 was $0.3 million and $0.5 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. In February 2005, we agreed to extend the manufacturing agreement by one year through October 2006 and provide Merck an opportunity, upon twelve months' prior notice, to extend the agreement for an additional year through October 2007. As a result, we are recognizing the remaining $2.7 million deferred balance of Merck's capital improvement reimbursements as of December 31, 2004, as revenue as product is shipped to Merck, based upon our revised estimate of Merck's order quantities through October 2006.

Expenses:

Total operating expenses increased to $44.5 million in the first quarter of 2005 from $38.2 million in the same period of 2004. Operating expenses in the first quarter of 2005 include a total of $5.4 million of Stock Option Expense, as follows:

For the three months ended March 31,	**2005**			**2004**
(in millions)	**Expenses as Reported**	**Stock Option Expense**	**Expenses exclusive of Stock Option Expense**	**Expenses as Reported**
Expenses				
Research and development	$ 35.9	$ 3.4	$ 32.5	$ 32.2
Contract manufacturing	2.5	—	2.5	2.2
General and administrative	6.1	2.0	4.1	3.8
Total operating expenses	$ 44.5	$ 5.4	$ 39.1	$ 38.2

In addition, $0.2 million of Stock Option Expense was capitalized into inventory, for a total of $5.6 million of Stock Option Expense recognized in the first quarter of 2005. Stock Option Expense was not included in operating expenses in the first quarter of 2004, as reported in our Statement of Operations. In the first quarter of 2004, had we adopted the fair value based method of accounting for stock-based employee compensation under the

provisions of SFAS No. 123, Stock Option Expense would have totaled $8.9 million. The decrease in total Stock Option Expense of $3.3 million in the first quarter of 2005 was primarily due to the lower exercise prices of option grants made by us in December 2004 and, in connection with our stock option exchange program, in January 2005. Exercise prices of these option grants were generally equal to the fair market value of our Common Stock on the date of grant.

Research and Development Expenses:

Research and development expenses, exclusive of Stock Option Expense, increased slightly to $32.5 million in the first quarter of 2005 from $32.2 million in the same period of 2004. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2005 and 2004:

For the three months ended March 31,	**2005**			**2004**
(in millions)				
Research and development expenses	**Expenses as Reported**	**Stock Option Expense**	**Expenses exclusive of Stock Option Expense**	**Expenses as Reported (2)**
Payroll and benefits	$ 14.4	$ 3.0	$ 11.4	$ 10.1
Clinical trial expenses	2.1	—	2.1	3.4
Clinical manufacturing costs (1)	9.0	0.4	8.6	8.3
Research and preclinical development costs	4.9	—	4.9	5.0
Occupancy and other operating costs	5.5	—	5.5	5.4
Total research and development	$ 35.9	$ 3.4	$ 32.5	$ 32.2

(1) Represents the full cost of manufacturing drug for use in research, preclinical development and clinical trials, including related payroll and benefits, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility.

(2) In 2004, research and development expenses as reported in our Statement of Operations did not include Stock Option Expense.

Payroll and benefits, exclusive of Stock Option Expense, increased $1.3 million in the first quarter of 2005 compared to the same period in 2004 as we added research and development personnel to support our clinical and research programs, especially for the VEGF Trap and IL-1 Trap. Clinical trial expenses decreased $1.3 million in the first quarter of 2005 compared to the same period in 2004 due to the completion of our IL-4/13 Trap phase 1 trial and of various AXOKINE trials in 2004. These decreases were partially offset by higher clinical trial expenses related to our VEGF Trap and IL-1 Trap clinical programs. Clinical manufacturing costs, exclusive of Stock Option Expenses, increased $0.3 million in the first quarter of 2005 compared to the same period in 2004. In 2005, higher costs for manufacturing IL-1 Trap clinical supplies were largely offset by lower costs for manufacturing VEGF Trap clinical supplies. In the first quarter of 2005, research and preclinical development costs decreased slightly by $0.1 million and occupancy and other operating costs increased slightly by $0.1 million compared to the same period in 2004.

Contract Manufacturing Expenses:

Contract manufacturing expenses was $2.5 million in the first quarter of 2005 and $2.2 million in the comparable quarter of 2004. We shipped similar quantities of product to Merck each quarter.

General and Administrative Expenses:

General and administrative expenses, exclusive of Stock Option Expense, increased to $4.1 million in the first quarter of 2005 from $3.8 million in the same period of 2004. In 2005, we incurred higher administrative personnel and facility costs, and higher accounting and other professional fees, primarily related to our efforts to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Other Income and Expense:

In January 2005, we and sanofi-aventis amended our collaboration agreement to exclude rights to develop and commercialization the VEGF Trap for eye diseases through local delivery systems. In connection with the amendment, sanofi-aventis made a one-time $25.0 million payment to us, which was recognized as other contract income in the first quarter of 2005. 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 increased to $2.2 million in the first quarter of 2005 from $1.1 million in the same period of 2004 due primarily to higher effective interest rates on investment securities in 2005. Interest expense decreased slightly to $3.0 million in the first quarter of 2005 from $3.1 million in the same period of 2004. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

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 past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Novartis, Procter & Gamble, and Merck, and investment income.

Change in Classification

We have revised the classification of our investments in auction rate securities from cash and cash equivalents to short-term investments in our previously issued financial statements. Auction rate securities are securities that have stated maturities beyond three months, but are priced and traded as short-term investments due to the liquidity provided through the auction mechanism that generally resets interest rates every 28 or 35 days. The change in classification resulted in a decrease in cash and cash equivalents and corresponding increase in short-term marketable securities at each balance sheet date. In addition, we revised our statements of cash flows to reflect the purchases and sales of these securities as investing activities rather than as a component of cash and cash equivalents. This change in classification had no impact on our previously reported current assets, net income (loss), or cash flows from operations. We held no auction rate securities at March 31, 2005.

The impact of the revision to the classification of our investments in auction rate securities on previously reported amounts for cash and cash equivalents and short-term marketable securities at December 31, 2004 and 2003, and cash flows provided by (used in) investing activities for the three month, six month, and nine month periods ended March 31, 2004, June 30, 2004, and September 30, 2004, respectively, and the years ended December 31, 2004 and 2003, is as follows:

Balance Sheet Impact at December 31, 2004 and 2003
(in millions)

	2004	2003
As originally reported:		
Cash and cash equivalents	$ 101.2	$ 118.3
Short-term marketable securities	194.8	164.6
Total	$ 296.0	$ 282.9
Revised to reflect auction rate securities as short-term investments:		
Cash and cash equivalents	$ 95.2	$ 97.5
Short-term marketable securities	200.8	185.4
Total	$ 296.0	$ 282.9

Statement of Cash Flows Impact for the three month, six month, and nine month periods ended March 31, June 30, and September 30, 2004, respectively, and the years ended December 31, 2004 and 2003

(in millions)	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004	December 31, 2003
As originally reported:					
Cash flows provided by (used in) investing activities	$ 70.2	$ 1.2	$ (12.1)	$ (4.6)	$ (63.8)
Revised to reflect auction rate securities as short-term investments:					
Cash flows provided by (used in) investing activities	$ 73.2	$ 4.2	$ (4.7)	$ 10.2	$ (49.6)

These revised amounts, as applicable, are reflected in this Quarterly Report on Form 10-Q for the period ended March 31, 2005, and will be included in our Quarterly Reports on Form 10-Q for the periods ended June 30 and September 30, 2005 and our Annual Report on Form 10-K for the year ended December 31, 2005.

Three Months Ended March 31, 2005 and 2004

Cash (Used in) Provided by Operations:

At March 31, 2005, we had $380.5 million in cash, cash equivalents and marketable securities compared with $348.9 million at December 31, 2004. In January 2005, we received two $25.0 million payments from sanofi-aventis. One payment was related to a VEGF Trap clinical milestone that was earned in December 2004. The second payment related to changes to our collaboration agreement with sanofi-aventis that were made in January 2005.

In the first quarter of 2005, our net loss was $4.1 million but cash provided by our operations was $33.1 million, principally due to receipts during the quarter from sanofi-aventis for (i) reimbursement of VEGF Trap development expenses incurred by us and (ii) the $25.0 million clinical milestone payment earned in December 2004. In addition, our net loss in the first quarter of 2005 included $5.9 million of non-cash stock-based employee compensation costs, of which $5.4 million represents Stock Option Expense resulting from our adoption of SFAS No. 123 in January 2005. In the first quarter of 2004, our net income was $64.5 million but we used $18.6 million of cash in operations. The difference between net income and cash usage was primarily due to above-described $42.75 million of other contract income, which was receivable from Novartis at the end of the first quarter of 2004 (and paid in April 2004) and the recognition of $39.9 million of non-cash deferred and research progress payment revenue pursuant to our agreement with Novartis.

Cash Provided by Investing Activities:

Net cash provided by investing activities decreased to $18.4 million in the first quarter of 2005 from $73.2 million in the same period in 2004, due primarily to a decrease in sales or maturities of marketable securities, net of purchases. In the first quarter of 2005, sales or maturities of marketable securities exceeded purchases by $19.8 million, whereas in the first quarter of 2004, sales or maturities of marketable securities exceeded purchases by $74.2 million.

Cash Provided by Financing Activities:

Cash provided by financing activities decreased to $1.0 million in the first quarter of 2005 from $4.1 million in the same period in 2004. In accordance with our collaboration agreement with Novartis, we elected to fund our share of 2003 IL-1 Trap development expenses through a loan from Novartis that was forgiven in March 2004 upon our achievement of a pre-defined IL-1 Trap development milestone. In the first quarter of 2004, we drew $3.8 million, excluding interest, against this loan facility for expenses incurred during 2003.

Sanofi-aventis Agreement:

In January 2005, we and sanofi-aventis amended our collaboration agreement to exclude rights to develop and commercialize the VEGF Trap for eye diseases through local delivery systems. In connection with this amendment, sanofi-aventis made a one-time $25.0 million payment to us. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights for and profits on sales, if any, of the VEGF Trap for disease indications included in our collaboration.

We have agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap. Under the collaboration agreement, as amended, 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 sanofi-aventis. If the collaboration becomes profitable, we will reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, 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. In addition, if the first commercial sale of a VEGF Trap product for diseases of the eye through local delivery systems predates the first commercial sale of a VEGF Trap product under the collaboration, we will begin reimbursing sanofi-aventis for up to $7.5 million of VEGF Trap development expenses commencing two years after such initial commercialization outside the collaboration in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $1.6 million and $0.7 million for the first three months of 2005 and 2004, respectively. During the remainder of 2005, we expect to incur approximately $7 million to $9 million in capital expenditures which primarily consists of equipment for our expanded manufacturing, research, and development activities.

Critical Accounting Policies and Significant Judgments and Estimates

There were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2004, during the quarter ended March 31, 2005.

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 for the remainder of 2005 approximately 55%-65% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, IL-1 Trap, and IL-4/13 Trap; approximately 20%-30% of our expenditures will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2005 will be used for capital expenditures and general corporate purposes..

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. For example, our agreements with Procter & Gamble and Serono, S.A. expire in 2005. 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 sanofi-aventis collaboration agreement, if the collaboration becomes profitable, we will reimburse sanofi-aventis for 50% of the VEGF Trap development expenses, including 50% of the $25.0 million payment received in connection with amending our collaboration agreement in January 2005, 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. In addition, if the first commercial sale of a VEGF Trap product for diseases of the eye through local delivery systems predates the first commercial sale of a VEGF Trap product under the collaboration, we will begin reimbursing sanofi-aventis for up to $7.5 million of VEGF Trap development expenses commencing two years after such initial commercialization outside the collaboration in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs. Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

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 mid-2007. 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 March 31, 2005, 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. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to $200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. 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 December 2004, the Financial Accounting Standards Board issued SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS No. 123R establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS No. 123R is effective for fiscal

years beginning after June 15, 2005. We will be required to adopt SFAS No. 123R effective for the fiscal year beginning January 1, 2006, and intend to do so using the modified prospective method. Under the modified prospective method, compensation cost is recognized beginning with the effective date based on (a) the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. Although the impact of adopting SFAS No. 123R has not yet been quantified, management believes that the future adoption of this standard may 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 actual events 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 described 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 March 31, 2005, we had a cumulative loss of $494.0 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. Our agreements with Procter & Gamble and Serono expire in 2005. Our agreement with Merck is scheduled to expire before the end of 2006, unless extended for one additional year by Merck. The expiration of these agreements will result in a significant loss of revenue to the Company, which may negatively affect our business, operating results, and financial condition.

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 mid-2007; 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 our 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.

We have adopted, effective January 1, 2005, the fair market value based method of accounting for stock-based employee compensation. This will materially increase operating expenses in our Statement of Operations, primarily due to non-cash compensation costs related to stock options.

We have adopted, effective January 1, 2005, the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS No. 123, *Accounting for Stock Based Compensation*, using the modified prospective method as described in SFAS No. 148, *Accounting for Stock Based Compensation – Transition and Disclosure*. As a result, we have begun recognizing expense in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant over the vesting period of the awards. Although the impact of adopting SFAS No. 123 has not been quantified for the full year 2005, in the first quarter of 2005, non-cash stock-based employee compensation expense of $5.4 million related to stock options awards was recognized in operating expenses in our Statement of Operations, which decreased our basic net income per share by $0.09 per share. Also, if we had adopted SFAS No. 123 effective January 1, 2004, our net income for the full year 2004 would have decreased by approximately $33.6 million and our basic net income per share in 2004 would have been $0.15 per share instead of $0.75 per share.

In addition, in December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, which is a revision of SFAS No. 123 and supersedes APB No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123R requires the recognition of compensation expense in an amount

equal to the fair value of share-based payments (including stock options) issued to employees. We will be required to adopt SFAS No. 123R effective for the fiscal year beginning January 1, 2006. The impact of adopting SFAS No. 123R has not yet been quantified.

The negative impact on our income (loss) as a result of adopting SFAS No. 123 as of January 1, 2005, and subsequently adopting SFAS No. 123R commencing January 1, 2006, may negatively affect our stock price.

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 infusion or by intravitreal 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.

In October 2003, we reported results from the first phase 2 trial of our IL-1 Trap in rheumatoid arthritis. We plan to conduct large-scale rheumatoid arthritis trials 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. 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. The higher doses may affect the safety and/or tolerability of the IL-1 Trap, which could delay or prevent its being approved for marketing and sale and could limit its commercial potential if the product candidate is ever approved.

We intend to study our lead product candidates, the VEGF Trap and IL-1 Trap, in a wide variety of indications in so-called "proof of concept" studies. We intend to study the VEGF Trap in a variety of cancer settings and ophthalmologic indications and the IL-1 Trap in a wide variety of inflammatory disorders. The specific indications were selected based on available preclinical and clinical data from medical publications, our product candidates, and competitive agents. The purpose of these exploratory "proof of concept" studies is to identify what diseases, if any, are best suited for treatment with these product candidates. However, it is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied in these "proof of concept" studies.

In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications studied in these early-stage trials.

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 fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we intend to study higher doses of the IL-1 Trap after a previous phase 2 trial of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

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 the desired indication(s) could harm the development of the product candidate(s), 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 conducted to date, 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. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they

are made available to patients after approval. 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 risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for either the treatment of cancer or diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with rheumatoid arthritis and other inflammatory diseases and disorders. Like TNF-antagonists such as EnbrelÒ (a registered trademark of Amgen) and RemicadeÒ (a registered trademark of Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the IL-1 Trap.

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. Subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap develop antibodies to the product candidate.

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 United States Food and Drug Administration (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, purported class action securities lawsuits were commenced against us and certain of our 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. On February 1, 2005, the Court denied our motion to dismiss the consolidated amended complaint. We believe the lawsuit is without merit and intend to continue to defend the action vigorously. Because we do not believe that a loss is probable, no legal reserve has been established. However, we cannot assure investors that we will be successful in defending this action, or that the amount of any settlement or judgment in this action will not exceed the coverage limits of our directors' and officers' liability insurance policies. If we are not successful in defending this action, our business and financial condition could be adversely affected. In addition, whether or not we are successful, the defense of this action may divert attention of our management and other resources that would otherwise be engaged in running our business.

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.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and The Nasdaq Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these increased costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2004, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2004. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

On February 27, 2004, Novartis Pharma AG 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 sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap. If the VEGF Trap program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, 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 sanofi-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. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time. If sanofi-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 sanofi-aventis

collaboration agreement would create new and additional risks to the successful development of the VEGF Trap.

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 sanofi-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 could 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, 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, product packagers, 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 have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, which expires in October 2006 unless extended for one additional year by 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 business and future prospects.

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 for 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 obtain regulatory approval for and 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 our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap, should it be approved in the future by regulatory authorities for marketing. 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 the VEGF Trap, IL-1 Trap, and IL-4/13 Trap, 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 our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

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 or the market for our product candidates may be too small to support commercialization or sufficient profitability.

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 enhance their competitive position 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 for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Eyetech Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. 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 and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and, if approved by the FDA, the Novartis phase 3 tyrosine kinase, because doctors and patients will have significant experience using these medicines.

The market for eye diseases is also very competitive. Eyetech Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for age-related macular degeneration. Novartis and Genentech are collaborating on another VEGF inhibitor for the treatment of eye diseases that is in phase 3 development. The marketing approval of the Eyetech/Pfizer VEGF inhibitor and the potential approval of the Novartis/Genentech VEGF antibody makes it more difficult for us to successfully develop the VEGF Trap in eye diseases. In addition, even if the VEGF Trap is ever approved for sale for the treatment of eye diseases, it will be difficult for our drug to compete against the Eyetech/Pfizer drug and, if approved by the FDA, the Novartis/Genentech phase 3 VEGF antibody, because doctors and patients will have significant experience using these medicines

The markets for both rheumatoid arthritis and asthma are very competitive. Several highly successful medicines are available for these diseases. Examples in rheumatoid arthritis include the TNF-antagonists Enbrel® (a registered trademark of Amgen), Remicade® (a registered trademark of Centocor), and Humira® (a registered trademark of Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (a registered trademark of Amgen). Examples in asthma include 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 and other marketed therapies 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. For example, Vertex Pharmaceuticals Incorporated is developing an oral cytokine inhibitor of interleukin-1 beta converting enzyme (ICE). 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.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS*-1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

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 examine 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.

Risk 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 that they 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.

We are aware of patents, allowed patent applications, and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap, which represents a potential competitive threat to Genentech’s VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation could materially harm our business either by requiring us to seek a license or resulting in our inability to develop and sell the VEGF Trap.

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 is 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 and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 15, 2005, our eight largest shareholders, which include sanofi-aventis and Novartis, beneficially owned 58.6% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 15, 2005. As of that date, Novartis owned 7,527,050 shares of Common Stock, representing approximately 14.0% of the shares of Common Stock then outstanding. These shares owned by Novartis are eligible to be sold pursuant to Rule 144(k) under the Securities Act of 1933, as amended, without registration, without regard to the volume, manner-of-sale, or other limitations set forth in Rule 144 under such Act, and without any contractual restrictions on sale.

As of April 15, 2005, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.2% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, these shares may generally not be sold or otherwise transferred until after September 5, 2005, and for one year after that date, sanofi-aventis may sell no more than 250,000 shares in any calendar quarter. After September 5, 2006, sanofi-aventis may sell no more than 500,000 shares in any calendar quarter. If Novartis or sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis and Novartis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 15, 2005, holders of Class A Stock held 4.2% of all shares of Common Stock and Class A Stock then outstanding, and had 30.5% of the combined voting power of all of Common Stock and Class A Stock then outstanding assuming, in each case, the exercise of all options held by such persons which are exercisable within 60 days of April 15, 2005. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 15, 2005:

- our current officers and directors beneficially owned 13.8% of our outstanding shares of Common Stock (assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 15, 2005) and 34.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 15, 2005; and

- our eight largest shareholders beneficially owned 58.6% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 15, 2005. In addition, these eight shareholders held 63.9% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 15, 2005.

The anti-takeover effects of provisions of our charter, by-laws, and rights agreement, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws, our rights agreement and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

We have a shareholder rights plan which could make it more difficult for a third party to acquire us without the support of our board of directors and principal shareholders. In addition, many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

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 estimated that a one percent change in interest rates would result in an approximately $1.2 million and $0.9 million change in the fair market value of our investment portfolio at March 31, 2005 and 2004, respectively.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by our in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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. On February 1, 2005, the Court denied our motion to dismiss the consolidated amended complaint. We believe the lawsuit is without merit and intend to continue to defend the action vigorously. Because we do not believe that a loss is probable, no legal reserve has been established. However, we cannot assure investors that we will be successful in defending this action, or that the amount of any settlement or judgement in this action will not exceed the coverage limits of our directors' and officers' liability insurance policies. If we are not successful in defending this action, our business and financial condition could be adversely affected. In addition, whether or not we are successful, the defense of this action may divert attention of our management and other resources that would otherwise be engaged in running our business.

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 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	- Statement re: computation of ratio of earnings to combined fixed charges.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	- Certification of 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.

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: May 9, 2005

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

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Three months ended March 31,
	2000	2001	2002	2003	2004	2005
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	$ (17,077)	$ (75,178)	$ (124,350)	$ (107,395)	$ 41,565	$ (4,124)
Fixed charges	1,309	3,888	13,685	14,108	14,060	3,431
Amortization of capitalized interest	—	—	—	33	78	19
Interest capitalized	—	—	(222)	(276)	—	—
Adjusted earnings	$ (15,768)	$ (71,290)	$ (110,887)	$ (93,530)	$ 55,703	$ (674)
Fixed charges:						
Interest expense	$ 281	$ 2,657	$ 11,859	$ 11,932	$ 12,175	$ 3,013
Interest capitalized	—	—	222	276	—	—
Assumed interest component of rental charges	1,028	1,231	1,604	1,900	1,885	418
Total fixed charges	$ 1,309	$ 3,888	$ 13,685	$ 14,108	$ 14,060	$ 3,431
Ratio of earnings to fixed charges	(A)	(A)	(A)	(A)	3.96	(A)

(A) Due to the registrant's losses for the years ended December 31, 2000, 2001, 2002, and 2003 and for the three months ended March 31, 2005, the ratio coverage was less than 1:1. To achieve a coverage ration of 1:1, the registrant must generate additional earning of the amounts shown in the table below.

	Years ended December 31,					Three months ended March 31,
	2000	2001	2002	2003	2004	2005
Coverage deficiency	$ 17,077	$ 75,178	$ 124,572	$ 107,638	—	$ 4,105

Exhibit 31.1

Certification of CEO 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 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principals;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this 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

d) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 the 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: May 9, 2005

/s/ Leonard S. Schleifer

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

Exhibit 31.2

Certification of 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, 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 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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, including its consolidated subsidiaries, is made known to us by others within the those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principals;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this 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

d) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 the 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: May 9, 2005

/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 ended March 31, 2005 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
May 9, 2005

/s/ Murray A. Goldberg
Murray A. Goldberg
Chief Financial Officer
May 9, 2005