

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2003

OR

() TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of
incorporation or
organization)

777 Old Saw Mill River Road
Tarrytown, New York

(Address of principal executive offices)

13-3444607

(I.R.S. Employer Identification No.)

10591-6707

(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No []

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of July 31, 2003:

Class of Common Stock	Number of Shares
Class A Stock, \$0.001 par value	2,406,548
Common Stock, \$0.001 par value	49,711,020

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CERTIFICATION

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements****REGENERON PHARMACEUTICALS, INC.****Condensed Balance Sheets at June 30, 2003 and December 31, 2002 (Unaudited)***(In thousands, except share data)*

	June 30, 2003	December 31, 2002
ASSETS		
Current assets		
Cash and cash equivalents	\$ 129,659	\$ 80,077
Marketable securities	133,302	173,282
Restricted marketable securities	10,913	10,912
Accounts receivable	7,871	4,017
Prepaid expenses and other current assets	3,063	1,829
Inventory	10,342	6,831
Total current assets	295,150	276,948
Marketable securities	4,185	20,402
Restricted marketable securities	5,319	10,573
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	84,670	76,825
Other assets	6,223	6,826
Total assets	\$ 395,547	\$ 391,574
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 14,043	\$ 30,309
Deferred revenue, current portion	35,021	9,659
Capital lease obligations		150
Total current liabilities	49,064	40,118
Deferred revenue	3,493	5,475
Notes payable	200,000	200,000
Loan payable	5,147	
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;		
2,406,548 shares issued and outstanding in 2003		
2,491,181 shares issued and outstanding in 2002	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized;		
49,697,672 shares issued and outstanding in 2003		
41,746,133 shares issued and outstanding in 2002	50	42
Additional paid-in capital	622,931	573,184
Unearned compensation	(2,443)	(3,643)
Accumulated deficit	(482,921)	(424,075)
Accumulated other comprehensive income	224	471
Total stockholders' equity	137,843	145,981
Total liabilities and stockholders' equity	\$ 395,547	\$ 391,574

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

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.**
Condensed Statements of Operations (Unaudited)
(In thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2003	2002	2003	2002
Revenues				
Contract research and development	\$ 9,774	\$ 2,745	\$ 19,198	\$ 5,435
Contract manufacturing	758	2,824	1,470	5,075
	<u>10,532</u>	<u>5,569</u>	<u>20,668</u>	<u>10,510</u>
Expenses				
Research and development	33,717	30,701	68,107	56,178
Contract manufacturing	259	1,861	925	3,120
General and administrative	3,488	2,956	6,947	6,356
	<u>37,464</u>	<u>35,518</u>	<u>75,979</u>	<u>65,654</u>
Loss from operations	<u>(26,932)</u>	<u>(29,949)</u>	<u>(55,311)</u>	<u>(55,144)</u>
Other income (expense)				
Investment income	1,101	2,553	2,309	5,325
Interest expense	(2,905)	(3,027)	(5,844)	(6,049)
	<u>(1,804)</u>	<u>(474)</u>	<u>(3,535)</u>	<u>(724)</u>
Net loss	<u>(\$ 28,736)</u>	<u>(\$ 30,423)</u>	<u>(\$ 58,846)</u>	<u>(\$ 55,868)</u>
Net loss per share amounts, basic and diluted	<u>(\$0.58)</u>	<u>(\$0.69)</u>	<u>(\$1.25)</u>	<u>(\$1.27)</u>

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

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REGENERON PHARMACEUTICALS, INC.
Condensed Statement of Stockholders' Equity (Unaudited)
For the six months ended June 30, 2003
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation
	Shares	Amount	Shares	Amount		
Balance, December 31, 2002	2,491	\$ 2	41,746	\$42	\$573,184	(\$3,643)
Issuance of Common Stock in connection with exercise of stock options			300		1,076	
Issuance of Common Stock to Novartis Pharma AG			7,527	8	47,992	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(3)		(68)	68
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			43		747	
Conversion of Class A Stock to Common Stock	(85)		85			
Amortization of unearned compensation						1,132
Net loss						
Change in net unrealized gain on marketable securities						
Balance, June 30, 2003	2,406	\$ 2	49,698	\$50	\$622,931	(\$2,443)

	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Loss
Issuance of Common Stock in connection with exercise of stock options			1,076	
Issuance of Common Stock to Novartis Pharma AG			48,000	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			747	
Conversion of Class A Stock to Common Stock				
Amortization of unearned compensation			1,132	
Net loss	(58,846)		(58,846)	(\$58,846)
Change in net unrealized gain on marketable securities		(247)	(247)	(247)
Balance, June 30, 2003	(\$482,921)	\$ 224	\$137,843	(\$59,093)

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

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.**
Condensed Statements of Cash Flows (Unaudited)
(In thousands)

	Six months ended June 30,	
	2003	2002
Cash flows from operating activities		
Net loss	(\$58,846)	(\$55,868)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	4,967	4,236
Non-cash compensation expense	1,132	879
Changes in assets and liabilities		
Increase in accounts receivable	(3,854)	(11)
Decrease (increase) in prepaid expenses and other assets	42	(1,903)
Increase in inventory	(2,947)	(830)
Increase (decrease) in deferred revenue	23,380	(3,601)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(3,388)	1,455
Total adjustments	19,332	225
Net cash used in operating activities	(39,514)	(55,643)
Cash flows from investing activities		
Purchases of marketable securities	(82,273)	(194,705)
Purchases of restricted marketable securities	(5,523)	
Sales of marketable securities	136,781	76,533
Maturities of restricted marketable securities	11,023	5,500
Capital expenditures	(24,985)	(10,881)
Net cash provided by (used in) investing activities	35,023	(123,553)
Cash flows from financing activities		
Net proceeds from the issuance of stock	49,076	1,429
Borrowings under loan payable	5,147	
Capital lease payments	(150)	(252)
Net cash provided by financing activities	54,073	1,177
Net increase (decrease) in cash and cash equivalents	49,582	(178,019)
Cash and cash equivalents at beginning of period	80,077	247,393
Cash and cash equivalents at end of period	\$ 129,659	\$ 69,374

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

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”) have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company’s financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company’s financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2002 Condensed Balance Sheet data was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2002.

Certain reclassifications have been made to the financial statements for the three and six months ended June 30, 2002 to conform with the current period’s presentation.

2. Stock-based Employee Compensation

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

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

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

	Three months ended June 30,	
	2003	2002
Net loss, as reported	(\$28,736)	(\$30,423)
Add: Stock-based employee compensation expense included in reported net loss	545	440
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(10,997)	(11,548)
Pro forma net loss	(\$39,188)	(\$41,531)
Net loss per share amounts, basic and diluted:		
As reported	(\$0.58)	(\$0.69)
Pro forma	(\$0.79)	(\$0.95)

	Six Months ended June 30,	
	2003	2002
Net loss, as reported	(\$58,846)	(\$55,868)
Add: Stock-based employee compensation expense included in reported net loss	1,132	879
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(22,582)	(22,882)
Pro forma net loss	(\$80,296)	(\$77,871)
Net loss per share amounts, basic and diluted:		
As reported	(\$1.25)	(\$1.27)
Pro forma	(\$1.71)	(\$1.78)

For the purpose of the pro forma calculation, the fair value of each option granted from the Company's stock-based incentive plans during the three and six months ended June 30, 2003 and 2002 was estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average fair value of the options granted during the three months ended June 30, 2003 and 2002 was \$9.16 and \$13.59, respectively. The weighted-average fair value of the options granted during the six months ended June 30, 2003 and 2002 was \$13.91 and \$17.13, respectively. The following tables summarize the assumptions used in computing the fair value of option grants.

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

	Three months ended June 30,	
	2003	2002
Expected volatility	80%	70%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.01-3.83%	3.98%-4.72%

	Six months ended June 30,	
	2003	2002
Expected volatility	80%	70%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.01-4.01%	3.98%-4.72%

Under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan, the Company awards shares of Restricted Stock. Restrictions on these shares generally lapse with respect to 25% of the shares every six months over approximately a two-year period. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to these awards. The amount is based on the fair market value of shares of the Company's Common Stock on the grant date of the Restricted Stock award and is expensed, on a pro rata basis, over the period that the restrictions lapse. For the three months ended June 30, 2003 and 2002, the Company recognized compensation expense related to Restricted Stock awards of \$545 and \$440, respectively. For the six months ended June 30, 2003 and 2002, the Company recognized compensation expense related to Restricted Stock awards of \$1,132 and \$879, respectively.

3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2003 and December 31, 2002 are \$1,359 and \$13,490, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2002 and December 31, 2001 are \$3,358 and \$1,946, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2002 and 2001 are \$747 and \$764, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2003 and 2002, the Company contributed 42,543 and 21,953 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

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

Included in marketable securities at June 30, 2003 and December 31, 2002 are \$570 and \$2,013, respectively, of accrued interest income. Included in marketable securities at June 30, 2002 and December 31, 2001 are \$3,039 and \$1,988, respectively, of accrued interest income.

4. Inventories

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

Inventories as of June 30, 2003 and December 31, 2002 consist of the following:

	June 30, 2003	December 31, 2002
Raw materials	\$ 456	\$ 357
Work-in-process	626	261 ⁽²⁾
Finished products	9,260 ⁽¹⁾	6,213 ⁽³⁾
	<u>\$10,342</u>	<u>\$6,831</u>

⁽¹⁾ Net of reserves of \$1,119.

⁽²⁾ Net of reserves of \$32.

⁽³⁾ Net of reserves of \$1,223.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2003 and December 31, 2002 consist of the following:

	June 30, 2003	December 31, 2002
Accounts payable	\$ 3,984	\$13,297
Accrued payroll and related costs	3,270	4,162
Accrued clinical trial expense	2,051	4,515
Accrued capital expenditures	688	4,322
Accrued expenses, other	1,758	1,721
Interest payable on convertible notes	2,292	2,292
	<u>\$14,043</u>	<u>\$30,309</u>

REGENERON PHARMACEUTICALS, INC.**Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)***6. Comprehensive Loss**

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended June 30, 2003 and 2002, the components of comprehensive loss are:

	Three Months Ended June 30,	
	2003	2002
Net loss	(\$28,736)	(\$30,423)
Change in net unrealized gain on marketable securities	(71)	397
Total comprehensive loss	(\$28,807)	(\$30,026)

For the six months ended June 30, 2003 and 2002, the components of comprehensive loss are:

	Six Months Ended June 30,	
	2003	2002
Net loss	(\$58,846)	(\$55,868)
Change in net unrealized gain on marketable securities	(247)	(400)
Total comprehensive loss	(\$59,093)	(\$56,268)

7. Collaboration and License Agreement

In March 2003, the Company entered into a collaboration agreement (the "Novartis Agreement") with Novartis Pharma AG ("Novartis") to jointly develop and commercialize the Interleukin-1 Cytokine Trap ("IL-1 Trap"). In connection with this agreement, Novartis made a non-refundable up-front payment of \$27.0 million and purchased \$48.0 million of newly issued unregistered shares of the Company's Common Stock. Regeneron issued 2,400,000 shares of Common Stock to Novartis in March 2003 and an additional 5,127,050 shares in May 2003 for a total of 7,527,050 shares based upon the average closing price of the Common Stock for the 20 consecutive trading days ending May 12, 2003.

Development expenses incurred during 2003 will be shared equally by the Company and Novartis. Regeneron may fund its share of 2003 development expenses through a loan (the "2003 Loan") from Novartis, which will bear interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly. The 2003 Loan and accrued interest thereon will be forgiven should certain defined pre-clinical and clinical milestones be reached; otherwise, such amounts are payable on July 1, 2004. As of June 30, 2003, the 2003 Loan balance due Novartis, including accrued interest, totaled \$5,147.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unless otherwise noted, dollars in thousands, except per share data)

Development expenses incurred subsequent to 2003 will be shared by the Company and Novartis, as set forth in the Novartis Agreement, with funding for Regeneron's share of these expenses available through another loan (the "Post-2003 Loan") from Novartis. Also, Regeneron's share of promotional expenses prior to product launch, as defined, may be funded through an additional loan (the "Promotion Expense Loan") from Novartis. These loans will bear interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly. The Post-2003 Loan and the Promotion Expense Loan, including accrued interest thereon, will be due five and three years, respectively, after the earlier of either the first commercial sale of an IL-1 Trap product in the United States or Europe or the effective date of termination of the agreement by Novartis.

Novartis has the right to terminate the agreement without cause with at least nine months advance notice.

The Company and Novartis will share co-promotion rights and profits on sales, if any, of the IL-1 Trap. In addition, the Company may receive up to \$275.0 million in milestone payments upon the receipt of specified regulatory approvals and the achievement of certain product revenues targets. Also, under the Novartis Agreement, the Company and Novartis each has the option to collaborate on the development and commercialization of additional defined IL-1 product candidates that Regeneron and Novartis are currently developing independently.

Revenue related to payments from Novartis, including the up-front payment of \$27.0 million, reimbursement of Novartis' share of Regeneron-incurred development expenses, forgiveness of any loans, and the initial milestone payment upon receipt of the first specified regulatory approval is being recognized as contract research and development revenue on a percentage of completion basis in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*. Further regulatory and product revenues milestone payments will be recognized if and when earned. For the three and six months ended June 30, 2003, the Company recognized \$7.0 million and \$13.7 million, respectively, of contract research and development revenue in connection with the Novartis Agreement. At June 30, 2003, amounts receivable from Novartis totaled \$4.3 million and deferred revenue was \$22.7 million.

8. Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. For the three and six months ended June 30, 2003 and 2002, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

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

<u>Three Months Ended June 30,</u>	<u>Net Loss, in thousands (Numerator)</u>	<u>Shares, in thousands (Denominator)</u>	<u>Per Share Amount</u>
2003:			
Basic and diluted	(\$28,736)	49,566	(\$0.58)
2002:			
Basic and diluted	(\$30,423)	43,914	(\$0.69)
<u>Six Months Ended June 30,</u>	<u>Net Loss, in thousands (Numerator)</u>	<u>Shares, in thousands (Denominator)</u>	<u>Per Share Amount</u>
2003:			
Basic and diluted	(\$58,846)	46,937	(\$1.25)
2002:			
Basic and diluted	(\$55,868)	43,868	(\$1.27)

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

	<u>Three Months Ended June 30,</u>	
	<u>2003</u>	<u>2002</u>
Options:		
Weighted average number, in thousands	11,334	9,471
Weighted average exercise price	\$ 21.44	\$21.48
Restricted Stock:		
Weighted average number, in thousands	172	97
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$30.25

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

	Six Months Ended June 30,	
	2003	2002
Options:		
Weighted average number, in thousands	11,433	9,447
Weighted average exercise price	\$ 21.37	\$21.38
Restricted Stock:		
Weighted average number, in thousands	175	97
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$30.25

9. 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 the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements.

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

The table below presents information about reported segments for the three and six months ended June 30, 2003 and 2002:

	Three Months Ended June 30, 2003			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 9,774	\$758	—	\$ 10,532
Depreciation and amortization	2,418	— ⁽¹⁾	\$ 261	2,679
Interest expense	8	—	2,897	2,905
Net (loss) income	(27,439)	499	(1,796) ⁽²⁾	(28,736)
Capital expenditures	4,722	—	—	4,722

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

	Three Months Ended June 30, 2002			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 2,745	\$2,824	—	\$ 5,569
Depreciation and amortization	1,967	— ⁽¹⁾	\$ 261	2,228
Interest expense	15	1	3,011	3,027
Net (loss) income	(30,927)	962	(458) ⁽²⁾	(30,423)
Capital expenditures	7,656	14	—	7,670

	Six Months Ended June 30, 2003			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 19,198	\$ 1,470	—	\$ 20,668
Depreciation and amortization	4,445	— ⁽¹⁾	\$ 522	4,967
Interest expense	8	—	5,836	5,844
Net (loss) income	(55,864)	545	(3,527) ⁽²⁾	(58,846)
Capital expenditures	12,854	—	—	12,854
Total assets	88,860	14,023	292,664 ⁽³⁾	395,547

	Six Months Ended June 30, 2002			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 5,435	\$ 5,075	—	\$ 10,510
Depreciation and amortization	3,714	— ⁽¹⁾	\$ 522	4,236
Interest expense	26	2	6,021	6,049
Net (loss) income	(57,125)	1,953	(696) ⁽²⁾	(55,868)
Capital expenditures	12,258	35	—	12,293
Total assets	45,271	10,545	384,635 ⁽³⁾	440,451

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

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

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

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unless otherwise noted, dollars in thousands, except per share data)

10. 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. The complaints, which purport 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, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. The Company's management believes that the lawsuits are without merit. The ultimate outcome of these matters cannot presently be determined. Accordingly, no provision for any liability that may result upon the resolution of these matters has been made in the accompanying financial statements.

11. Commitments and Contingencies

In November 2002, the Financial Accounting Standards Board issued FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others, an interpretation of SFAS Nos. 5, 57 and 107 and Rescission of FASB Interpretation No. 34*. FIN 45 clarifies the requirements of SFAS No. 5, *Accounting for Contingencies*, relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. Adoption of FIN 45 did not have a material impact on either the operating results or financial position of the Company.

The Company enters into indemnification provisions, normal and customary for companies in its industry sector, under its agreements with third parties in its ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless, and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company's product candidates, use of such product candidates or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these provisions is minimal. Accordingly, the Company has no liabilities recorded for these provisions as of June 30, 2003.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unless otherwise noted, dollars in thousands, except per share data)

12. Future Impact of Recently Issued Accounting Standards

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 (“SFAS No. 150”), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 specifies that instruments within its scope embody obligations of the issuer and that, therefore, the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments; (2) obligations to repurchase the issuer’s equity shares by transferring assets and (3) certain obligations to issue a variable number of shares. SFAS No. 150 defines a “freestanding financial instrument” as a financial instrument that (1) is entered into separately and apart from any of the entity’s other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, SFAS No. 150 is effective immediately. For all other instruments of public companies, SFAS No. 150 goes into effect at the beginning of the first interim period beginning after June 15, 2003. The Company does not expect the adoption of SFAS No. 150 to have a material impact on its financial statements.

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

General

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

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic products for the treatment of serious medical conditions. Our clinical and pre-clinical pipeline includes product candidates for the treatment of obesity, rheumatoid arthritis and other inflammatory conditions, cancer and related disorders, allergies, asthma, and other diseases and disorders. Developing and commercializing new medicines entails risk and significant expense. Since inception, we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to combine our strong foundation in 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 have the potential to address a variety of unmet medical needs. 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 in which a specific gene is removed (referred to as “knock-out”) or is overproduced (referred to as “transgenic”). We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Below is a summary of our leading clinical and pre-clinical research programs. With the exception of the IL-1 Trap, which we are developing in collaboration with

Novartis Pharma AG, we retain sole ownership and marketing rights for each of these programs and currently are developing them independently of any corporate partners.

- **AXOKINE®:** Acts on the brain region regulating food intake and energy expenditure and is being developed for the treatment of obesity. In March 2003, we reported data from the 12-month treatment period of our initial Phase III pivotal trial of AXOKINE. This trial enrolled approximately 2000 patients and involved a 12-month treatment period in which subjects received daily subcutaneous self-injections of placebo or AXOKINE. The study demonstrated that subjects receiving AXOKINE experienced a greater average weight loss than those receiving placebo (6.2 lbs. vs. 2.6 lbs, $p < .001$) and that a greater proportion of AXOKINE-treated subjects lost at least 5 percent of their initial body weight compared with placebo-treated subjects (25.1 percent vs. 17.6 percent, $p < .001$). Although the Phase III study met its primary endpoints and many individuals achieved a medically meaningful weight loss, the average weight loss was small and limited by the development of antibodies. The study also showed that AXOKINE had a favorable safety and tolerability profile. The treatment period in this study is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. The extension phase is expected to be completed in the first quarter of 2004.

In April 2003, we announced the results of a 12-week Phase II clinical trial to assess the safety and efficacy of AXOKINE in overweight and obese individuals with type 2 diabetes mellitus. The study showed that treatment with AXOKINE resulted in statistically significant and dose-dependent weight loss, which was in line with the weight loss observed in the Phase III pivotal trial at the same 12-week time point. This trial recently completed a 12-week open-label extension phase.

- **INTERLEUKIN-1 CYTOKINE TRAP (IL-1 Trap):** Protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. IL-1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In July 2002, we announced the initiation of a dose-ranging Phase II trial to study the safety and efficacy of the IL-1 Trap in approximately 200 people with rheumatoid arthritis. This trial was fully enrolled in the first quarter of 2003. Subjects in the study received, in a double-blind manner, either placebo or one of three different dose levels of the IL-1 Trap. The results from this trial are expected to be available in the second half of 2003. In March 2003, we entered into an agreement with Novartis to jointly develop and commercialize the IL-1 Trap throughout the world, with the exception of Japan, where product rights remain with Regeneron.
- **VEGF TRAP:** Protein-based therapeutic candidate designed to bind Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF) and prevent its interaction with cell surface receptors. VEGF is required for the growth of blood vessels that are needed for tumors to grow and is

a potent regulator of vascular permeability and leak. In 2001, we initiated a dose-escalation Phase I clinical trial designed to assess the safety and tolerability of the VEGF Trap in subjects with solid tumor malignancies and/or non-Hodgkin's lymphoma. This trial continues to test increasing doses of VEGF Trap delivered by subcutaneous injection as per the protocol and is expected to be completed in the first half of 2004. An additional study of VEGF Trap delivered intravenously is expected to begin by the end of this year and further studies of the VEGF Trap in cancer are being planned. We are also evaluating the VEGF Trap in pre-clinical studies as a potential treatment for diseases of the eye. Regeneron is considering a number of strategies, including possible collaborative arrangements, to accelerate development of the VEGF Trap.

- **INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/13 Trap):** Protein-based product candidate designed to bind the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines and prevent their interaction with cell surface receptors. IL-4 and IL-13 are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. In October 2002, we initiated a Phase I trial for the IL-4/13 Trap in adult subjects with mild to moderate asthma. This placebo-controlled, double-blind, dose escalation study is designed to assess the safety and tolerability of the IL-4/13 Trap. The trial is expected to be completed in the second half of 2003. We are continuing our research on IL-4 and IL-13 in other inflammatory conditions beyond asthma, which may lead to new potential indications for the IL-4/13 Trap.
- **ANGIOPOIETINS:** A new family of growth factors that act specifically on the endothelium cells that line blood vessels. Angiopoietins may be useful for growing blood vessels in diseased hearts and other tissues with decreased blood flow and for repairing blood vessel leaks that cause swelling and edema in many different diseases such as stroke, diabetic retinopathy, and inflammatory diseases. We have an active pre-clinical research program covering this family of growth factors. We have not yet selected a specific molecule to advance into clinical development or a specific indication for development.

In addition, we have formed collaborations to advance other research and development efforts. We are conducting research with The Procter & Gamble Company in muscle diseases and other fields. We are also collaborating with Medarex, Inc. to discover, develop, and commercialize certain human antibodies as therapeutics. In partnership with Amgen Inc., we have development rights to Neurotrophin-3, or NT-3, a clinical compound for the treatment of constipating conditions, although there are no ongoing development activities for NT-3 at this time. In all of these research collaborations, we retain 50% of the commercialization rights.

Discussion of Second Quarter 2003 Activities

In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese subjects. The initial pivotal Phase III trial was a double-blind,

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randomized, placebo-controlled study that enrolled approximately 2,000 subjects at 65 sites across the United States. In March 2003, we reported data from the 12-month treatment period of the trial during which subjects received daily subcutaneous self-injections of placebo or AXOKINE at a dose of 1.0 microgram per kilogram of body weight (mcg/kg). The study demonstrated that subjects receiving AXOKINE experienced a greater average weight loss than those receiving placebo (6.2 pounds vs. 2.6 pounds, $p < .001$) and that a greater proportion of AXOKINE-treated subjects lost at least 5 percent of their initial body weight compared with placebo-treated subjects (25.1 percent vs. 17.6 percent, $p < .001$). AXOKINE also achieved statistically significant results in two of the three secondary endpoints, including the proportion of subjects losing at least 10% of their initial body weight. The study also showed that AXOKINE had a favorable safety and tolerability profile. The double-blind treatment period is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. As of June 30, 2003, the average treatment period for people in this trial was 20 months.

Although the results of the Phase III study were statistically significant, the average weight loss for the entire treatment group was small. AXOKINE-associated weight loss was limited by the development of antibodies in approximately two-thirds of the AXOKINE-treated subjects. In the patients who did not become resistant to AXOKINE treatment through the development of antibodies, the weight loss appeared in line with currently available treatments for obesity. A more complete discussion of the results of this trial is contained in our Annual Report on Form 10-K for the year ended December 31, 2002.

In April 2003, we announced the results of a 12-week Phase II clinical trial to assess the safety and efficacy of AXOKINE in 157 overweight and obese individuals with type 2 diabetes mellitus who were treated with placebo or AXOKINE at doses of 1.0 mcg/kg or 0.5 mcg/kg per day. Subjects who were treated with AXOKINE at the 1.0 mcg/kg dose with dietary counseling lost 6.5 pounds on average, while those treated with placebo and dietary counseling lost only 2.5 pounds ($p < .01$). Trends toward improvements in blood glucose and other metabolic parameters were also observed during this small, short-term study. AXOKINE was generally well tolerated with no AXOKINE-related serious adverse events. Approximately 90 percent of study participants completed the 12-week study. This trial recently completed a 12-week open-label extension phase.

In this trial in patients with type 2 diabetes, approximately one-third of the subjects who were treated with the 1.0 mcg/kg dose of AXOKINE had developed antibodies to AXOKINE at the twelve-week time point. In the recently completed Phase III study of AXOKINE in non-diabetic subjects, about half of AXOKINE-treated participants had developed antibodies at the 12-week time point. This lower incidence of antibodies observed in the Phase II study will need to be explored in a larger Phase III study in the diabetic population. In the Phase III one-year study, further weight loss beyond 12 weeks appeared to be limited in those people who developed antibodies.

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In addition, in July 2002, we completed enrollment for two trials, each of which includes approximately 300 subjects, which are evaluating the safety of intermittent treatment with AXOKINE and studying maintenance of weight loss following short-term treatment regimens. Results from these trials are expected to be available in the first half of 2004. In January 2003, we announced that AXOKINE had received fast track designation from the FDA for the treatment of severely obese people who are unresponsive to, intolerant of, or unsuitable candidates for certain FDA-approved medicines for the long-term treatment of obesity.

In July 2002, we announced the initiation of a dose-ranging Phase II study of the IL-1 Trap in subjects with rheumatoid arthritis. This trial enrolled approximately 200 subjects who received weekly self-injections of one of three fixed doses of IL-1 Trap or placebo for 12 weeks, followed by 10 weeks of off-treatment follow-up. The results from this trial are expected to be available in the second half of 2003. The IL-1 Trap is also being evaluated for potential uses in treating other inflammatory diseases.

In March 2003, we entered into a Collaboration, License and Option Agreement with Novartis Pharma AG to jointly develop and commercialize the IL-1 Trap in rheumatoid arthritis and other indications throughout the world with the exception of Japan, where product rights remain with Regeneron. We and Novartis will share equally in all profits from future sales of the IL-1 Trap in North America and Europe. In other markets, Novartis will be entitled to receive 75 percent of the profits and we will be entitled to 25 percent of the profits. We may co-promote the IL-1 Trap in all territories under the agreement. As part of the agreement, Novartis purchased \$48.0 million of Regeneron's common stock and made a non-refundable up-front payment of \$27.0 million. The agreement is described in greater detail in the section of this report titled "Liquidity and Capital Resources".

Antagonists for IL-4 and IL-13 may be therapeutically useful in a number of allergy and asthma-related conditions, including as an adjunct to vaccines where blocking IL-4 and IL-13 may help to elicit more of the desired type of immune response to the vaccine. We have developed both an IL-4 Trap and an IL-4/13 Trap, which is a single molecule that can block both interleukin-4 and interleukin-13. In October 2002, we initiated a Phase I clinical trial of a dual IL-4/13 Trap to assess the safety and tolerability of increasing dose levels in subjects with mild to moderate asthma. The Phase I trial is expected to end in the second half of 2003. We are continuing our research of IL-4 and IL-13 in other inflammatory conditions beyond asthma, which may lead to new potential indications for the IL-4/13 Trap.

In November 2001, we initiated a Phase I clinical trial designed to assess the safety and tolerability of VEGF Trap in patients with solid tumor malignancies and subjects with non-Hodgkin's lymphoma. The Phase I trial is an open-label study in subjects with advanced tumors and will evaluate the VEGF Trap in increasing dose levels. The study is being conducted at three clinical sites in the United States. Higher doses of VEGF Trap are expected to be studied as the trial progresses and we anticipate the study to end in the first half of 2004. An additional study of VEGF Trap delivered

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intravenously is expected to begin by the end of this year and further studies of the VEGF Trap in cancer are being planned. We are also evaluating the VEGF Trap in preclinical studies as a potential treatment for diseases of the eye. Regeneron is considering a number of strategies, including possible collaborative arrangements, to accelerate development of the VEGF Trap.

A minority of all research and development programs ultimately results in commercially successful pharmaceutical drugs; it is not possible to predict whether any program will succeed until it actually produces a medicine that is commercially marketed for a significant period of time. In addition, in each of the areas of our independent and collaborative activities, other companies and entities are actively pursuing competitive paths toward similar objectives. The results of Regeneron's and its collaborators' past activities in connection with the research and development of AXOKINE, Cytokine Traps, Angiopoietins, cancer, abnormal bone growth, muscle atrophy, small molecules, NT-3, and other programs or areas of research or development do not necessarily predict the results or success of current or future activities including, but not limited to, any additional preclinical or clinical studies. We cannot predict whether, when, or under what conditions any of our research or product candidates, including without limitation AXOKINE, IL-1 Trap, VEGF Trap, or IL-4/13 Trap will be shown to be safe or effective to treat any human condition or be approved for marketing by any regulatory agency. The delay or failure of current or future studies to demonstrate the safety or efficacy of its product candidates to treat human conditions or to be approved for marketing could have a material adverse impact on Regeneron. We discuss the risks associated with pharmaceutical drug development in the section of this report titled "Factors That May Affect Future Operating Results."

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

From inception on January 8, 1988 through June 30, 2003, we had a cumulative loss of \$482.9 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Our activities may expand over time and may require additional resources and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the timing of certain expenses and on the progress of our research and development efforts.

Results of Operations

Three months ended June 30, 2003 and 2002. Our total revenue increased to \$10.5 million for the second quarter of 2003 from \$5.6 million for the same period of 2002. Contract research and development revenue increased to \$9.8 million for the second quarter of 2003 from \$2.7 million for the same period of 2002, as we recognized \$7.0 million of revenue related to our IL-1 Trap collaboration with Novartis. We recognize revenue in connection with the collaboration using the percentage of completion method in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101). In addition, we recognized \$2.6 million of contract research and development revenue from Procter & Gamble in both the second quarter of 2003 and 2002 in connection with our long-term collaboration agreement. Contract manufacturing revenue, related to our long-term agreement with Merck & Co., Inc. to manufacture a vaccine intermediate at our Rensselaer, New York facility, decreased to \$0.8 million for the second quarter of 2003 from \$2.8 million for the same period of 2002, because product in inventory was not shipped to Merck during the first half of 2003. Shipments resumed in July 2003. Contract manufacturing revenue and the related manufacturing expense are recognized as product is accepted and shipped.

Our total operating expenses increased to \$37.5 million for the second quarter of 2003 from \$35.5 million for the same period of 2002. Research and development expenses increased to \$33.7 million for the second quarter of 2003 from \$30.7 million for the comparable period of 2002, as activity in our clinical research programs increased, especially related to our clinical programs for AXOKINE and the IL-1 Trap. Research and development expenses were 90% of total operating expenses in the second quarter of 2003, compared to 86% for the same period of 2002. Contract manufacturing expenses related to our long-term agreement with Merck decreased to \$0.3 million for the second quarter of 2003 from \$1.9 million for the same period of 2002, because product in inventory was not shipped to Merck during the first half of 2003. General and administrative expenses increased to \$3.5 million in the second quarter of 2003 from \$3.0 million for the same period of 2002, due primarily to increased administrative costs to support the Company's expanding development pipeline, higher insurance costs, and higher fees paid to outside service providers.

Investment income decreased to \$1.1 million for the second quarter of 2003 from \$2.6 million for the same period of 2002 due to lower effective interest rates on investment securities and lower levels of interest-bearing investments in the second quarter of 2003 as the Company funded its operations. Interest expense declined slightly to \$2.9 million for the second quarter of 2003 from \$3.0 million for the same period of 2002. 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.

Our net loss for the second quarter of 2003 was \$28.7 million, or \$0.58 per share (basic and diluted), compared to a net loss of \$30.4 million, or \$0.69 per share (basic and diluted), for the same period of 2002.

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Six months ended June 30, 2003 and 2002. Our total revenue increased to \$20.7 million for the six months ended June 30, 2003 from \$10.5 million for the same period in 2002. Contract research and development revenue increased to \$19.2 million for the six months ended June 30, 2003 from \$5.4 million for the same period of 2002, as we recognized \$13.7 million of revenue related to our IL-1 Trap collaboration with Novartis. We recognize revenue in connection with the collaboration using the percentage of completion method in accordance with SAB 101. In addition, we recognized \$5.3 million and \$5.2 million of contract research and development revenue from Procter & Gamble in the first six months of 2003 and 2002, respectively, in connection with our long-term collaboration agreement. Contract manufacturing revenue, related to our long-term agreement with Merck, decreased to \$1.5 million for the first half of 2003 from \$5.1 million for the same period of 2002, because product in inventory was not shipped to Merck during the first half of 2003. Shipments resumed in July 2003.

Our total operating expenses increased to \$76.0 million for the six months ended June 30, 2003 from \$65.7 million for the same period of 2002. Research and development expenses increased to \$68.1 million for the first six months of 2003 from \$56.2 million for the comparable period of 2002, as activity in our clinical research programs increased, especially related to our clinical programs for AXOKINE and the IL-1 Trap. Research and development expenses were 90% of total operating expenses in the first six months of 2003, compared to 86% for the same period of 2002. Contract manufacturing expenses related to our long-term agreement with Merck decreased to \$0.9 million for the six months ended June 30, 2003 from \$3.1 million for the same period of 2002, because product in inventory was not shipped to Merck during the first half of 2003. General and administrative expenses increased to \$6.9 million for the first six months of 2003 from \$6.4 million for the same period of 2002, due primarily to increased administrative costs to support the Company's expanding development pipeline, higher insurance costs, and higher fees paid to outside service providers.

Investment income decreased to \$2.3 million for the six months ended June 30, 2003 from \$5.3 million for the same period of 2002 due to lower effective interest rates on investment securities and lower levels of interest-bearing investments in the first half of 2003 as the Company funded its operations. Interest expense declined slightly to \$5.8 million for the first six months of 2003 from \$6.0 million for the same period of 2002. 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.

Our net loss for the six months ended June 30, 2003 was \$58.8 million, or \$1.25 per share (basic and diluted), compared to a net loss of \$55.9 million, or \$1.27 per share (basic and diluted), for the same period of 2002.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of equity securities, a private placement of convertible debt, revenue earned under our agreements with Amgen, Sumitomo Chemical Co., Ltd., Sumitomo

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Pharmaceuticals Company, Ltd., Merck, Procter & Gamble, and Novartis, and investment income.

In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. Novartis made a non-refundable up-front payment of \$27.0 million and purchased 7,527,050 newly issued unregistered shares of our common stock for \$48.0 million.

Development expenses incurred during 2003 will be shared equally by Regeneron and Novartis. We may fund our share of 2003 expenses through a loan from Novartis that will be forgiven, together with accrued interest, should certain pre-clinical and clinical milestones be reached and is otherwise payable on July 1, 2004. As of June 30, 2003, we have drawn \$5.1 million against this loan facility. In addition, at June 30, 2003, \$4.3 million was receivable from Novartis for their share of IL-1 Trap development expenses incurred by Regeneron during the second quarter of 2003.

After 2003, Novartis will be responsible for any additional pre-Phase III development expenses, and the companies will share Phase III development expenses and pre-launch expenses. Our share of these expenses may be funded through two additional loans from Novartis. The loan and accrued interest for our share of Phase III development expenses is repayable in full five years after the initial product launch of the IL-1 Trap or five years after termination of Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. The loan and accrued interest for our share of pre-launch expenses is repayable in full three years after the initial product launch of the IL-1 Trap or three years after termination of Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. Novartis has the right to terminate the collaboration agreement without cause with at least nine months advance notice.

We and Novartis will share co-promotion rights and profit on sales, if any, of the IL-1 Trap. In addition, we may receive up to \$275.0 million in milestone payments upon receipt of specified regulatory approvals in the United States and the European Union and the achievement of certain product revenues targets. Under the agreement, each company also has the right to elect to collaborate on the development and commercialization of certain other pre-clinical/early development IL-1 antagonists that we and Novartis currently are developing independently. Regeneron will continue to manufacture clinical supplies of the IL-1 Trap at our plant in Rensselaer, New York. Novartis will be responsible for providing commercial scale manufacturing capacity for the IL-1 Trap.

Under a long-term collaboration agreement, Procter & Gamble provides funding through December 2005 of \$2.5 million per quarter, plus adjustments for inflation, in support of our research efforts.

At June 30, 2003, we had \$283.4 million in cash, cash equivalents, marketable securities, and restricted marketable securities. We have no off-balance sheet financing arrangements and do not guarantee the obligations of any other entity. As of June 30, 2003, we had no established banking arrangements through which we could obtain short-

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term financing or a line of credit. We may seek additional funding through, among other things, future collaboration agreements and public or private financing. We cannot assure you that additional financing will be available to us or, if available, that it will be available on acceptable terms.

Our additions to property, plant, and equipment totaled \$12.9 million and \$12.3 million for the first six months of 2003 and 2002, respectively.

We expect to incur substantial funding requirements for, among other things, research and development activities (including preclinical and clinical testing), expansion and validation of manufacturing facilities, and the acquisition of equipment. We currently anticipate that for the remainder of 2003, approximately 30-50% of our expenditures will be directed toward the pre-clinical and clinical development of product candidates, including AXOKINE, IL-1 Trap, IL-4/13 Trap, VEGF Trap, and the angiopoietins; approximately 5-15% of our expenditures will be invested in expansion of our manufacturing facilities; approximately 10-20% of our expenditures will cover our basic research activities; approximately 5-15% of our expenditures will be directed toward the continued development of our novel technology platforms, including potential efforts to commercialize these technologies; and the remainder of our expenditures will be for general corporate purposes, including working capital. For the remainder of 2003, we expect to incur approximately \$10 million in capital expenditures for our expanded manufacturing and research and development activities.

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.

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 drug candidates, and the continuation, extent, and success of any collaborative research arrangements (including those with Procter & Gamble, Novartis, Medarex, Emisphere Technologies, Inc., and Amgen). Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above.

We believe that our existing capital resources will enable us to meet operating needs through at least the end of 2004. However, this is a forward-looking statement based on our current operating plan, and we cannot assure you that there will be no change in projected revenues or expenses that would lead to our capital being

consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Future Impact of Recently Issued Accounting Standards

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 (“SFAS No. 150”), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 specifies that instruments within its scope embody obligations of the issuer and that, therefore, the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments; (2) obligations to repurchase the issuer’s equity shares by transferring assets and (3) certain obligations to issue a variable number of shares. SFAS No. 150 defines a “freestanding financial instrument” as a financial instrument that (1) is entered into separately and apart from any of the entity’s other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, SFAS No. 150 is effective immediately. For all other instruments of public companies, SFAS No. 150 goes into effect at the beginning of the first interim period beginning after June 15, 2003. We do not expect the adoption of SFAS No. 150 to have a material impact on our financial statements.

Factors That May Affect Future Operating Results

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

- Delay, difficulty, or failure of a clinical trial of any of our product candidates, including clinical trials of our product candidates AXOKINE and the IL-1 Trap. If either or both of these product candidates fail to advance in the clinic, our

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business will be severely harmed and our stock price will be adversely affected. A clinical trial can fail or be delayed as a result of many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may also fail because it did not include a sufficient number of patients to detect the endpoint being measured. For example, the pending trials studying the maintenance of weight loss following short-term treatment regimens with AXOKINE may not have enrolled enough patients to detect statistically significant differences between patients treated with AXOKINE and those taking placebo following the post-treatment maintenance periods. These trials were designed before we had access to the data from the recently completed Phase III trial, which demonstrated that the magnitude of the average difference in weight loss observed between all AXOKINE-treated subjects and those taking placebo was small.

- In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our pharmaceutical candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune type" disease. Whether antibodies will be created can often not be predicted from preclinical experiments and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been successfully completed. Subjects who have received AXOKINE and the IL-1 Trap in clinical trials have developed antibodies.
- Delay, difficulty, or failure in obtaining regulatory approval for our products, including delays or difficulties in development because of insufficient proof of safety or efficacy or the failure to manufacture product candidates in accordance with FDA requirements.
- Delay, difficulty, or failure of our research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by us or others.
- Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, our agreements with Procter & Gamble and Novartis) and the resulting loss of research or other funding could have a material adverse effect on us and our operations.

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- Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.
- Competitive or market factors that may cause use of our products to be limited or otherwise fail to achieve broad acceptance.
- The ability to obtain, maintain, and prosecute intellectual property rights and the cost of acquiring in-process technology and other necessary intellectual property rights, either by license, collaboration, or purchase of another entity.
- Difficulties or high costs of obtaining adequate financing to fund the cost of developing and manufacturing product candidates through public or private offerings or collaborative arrangements.
- Amount and rate of growth of our general and administrative expenses, and the impact of unusual charges resulting from our ongoing evaluation of our business strategies and organizational structure.
- Failure of corporate partners to develop or commercialize successfully our products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between our corporate partners and us.
- Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology products in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.
- Difficulties in manufacturing sufficient amounts of our product candidates suitable for clinical testing or commercialization. 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 AXOKINE, IL-1 Trap, IL-4/13 Trap, and VEGF 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 product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates. For example, AXOKINE currently is formulated for delivery in single use vials. We are in the process of developing a formulation that may be used in multiple use vials. If we are unable to develop this multiple use vial formulation, potential future AXOKINE sales and profitability may be limited.

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

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

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

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patents that pertain to the use of Ciliary Neurotrophic Factor, or CNTF, for the treatment of obesity. AXOKINE is a modified form of CNTF.

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 one or more of our product candidates, which could severely harm our business.

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

Item 3. Quantitative and Qualitative Disclosure About Market Risk.

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent change in interest rates would result in an approximately \$0.5 million change in the fair market value of our investment portfolio at June 30, 2003.

Item 4. Controls and Procedures

(a) Disclosure Controls and Procedures. Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this report. Based upon the evaluation, our President and Chief Executive Officer along with our Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures are effective in timely alerting them to material information relating to Regeneron required to be included in our reports filed or submitted under the Exchange Act.

(b) Internal Control over Financial Reporting. There have not been any changes in our internal controls over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter to which this report relates that have materially affected, or are 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 its officers and directors in the United States District Court for the Southern District of New York. The complaints, which purport 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, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. We believe that the lawsuits are without merit.

Item 4. Submission of Matters to a Vote of Security Holders

On June 13, 2003, we conducted our Annual Meeting of Shareholders pursuant to due notice. A quorum being present either in person or by proxy, the shareholders voted on the following matters:

1. To elect four Directors to hold office for a three-year term as Class III directors, and until their successors are duly elected and qualified.
2. To approve the selection of PricewaterhouseCoopers LLP as independent accountants for our fiscal year ending December 31, 2003.

No other matters were voted on. The number of votes cast was:

	<u>For</u>	<u>Withheld Authority</u>
1. Election of Class II Directors		
Charles A. Baker	62,988,454	1,672,741
Michael S. Brown, M.D.	64,282,679	378,516
George L. Sing	64,282,679	378,516
Arthur F. Ryan	62,934,374	1,726,821

The terms of office of Leonard S. Schleifer, M.D., Ph.D., Eric M. Shooter, Ph.D., George D. Yancopoulos, M.D., Ph.D., Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., and P. Roy Vagelos, M.D. continued after the meeting.

	<u>For</u>	<u>Against</u>	<u>Abstain</u>
2. Approval of accountants	64,229,439	423,818	7,765

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

31 - Certification of CEO and CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

32 - Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

(b) Reports

Form 8-K, filed August 1, 2003: On August 1, 2003, we issued a press release announcing our second quarter 2003 financial and operating results.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 14, 2003

Regeneron Pharmaceuticals, Inc.

By: /s/ Murray A. Goldberg

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

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

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 is made known to us by others within the registrant, particularly during the period in which this quarterly 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 the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2003

By: /s/ Leonard S. Schleifer

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

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 is made known to us by others within the registrant, particularly during the period in which this quarterly 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 the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
-

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2003

By: /s/ Murray A. Goldberg

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

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ending June 30, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

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

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
August 14, 2003

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
August 14, 2003

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