



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 June 30, 2007

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  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of July 31, 2007:

Class of Common Stock	Number of Shares
Class A Stock, \$0.001 par value	2,260,266
Common Stock, \$0.001 par value	63,798,205

[Table of Contents](#)

REGENERON PHARMACEUTICALS, INC.  
Table of Contents  
June 30, 2007

**Page Numbers**

**PART I FINANCIAL INFORMATION**

**Item 1 Financial Statements**

<a href="#">Condensed balance sheets (unaudited) at June 30, 2007 and December 31, 2006</a>	3
<a href="#">Condensed statements of operations (unaudited) for the three and six months ended June 30, 2007 and 2006</a>	4
<a href="#">Condensed statement of stockholders' equity (unaudited) for the six months ended June 30, 2007</a>	5
<a href="#">Condensed statements of cash flows (unaudited) for the six months ended June 30, 2007 and 2006</a>	6
<a href="#">Notes to condensed financial statements (unaudited)</a>	7-14

<a href="#">Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	15-39
--	-------

<a href="#">Item 3 Quantitative &amp; Qualitative Disclosure About Market Risk</a>	39
--	----

<a href="#">Item 4 Controls and Procedures</a>	39-40
--	-------

**PART II OTHER INFORMATION**

<a href="#">Item 1 Legal Proceedings</a>	40
--	----

<a href="#">Item 1A Risk Factors</a>	40-57
--------------------------------------	-------

<a href="#">Item 4 Submission of Matters to a Vote of Security Holders</a>	57
--	----

<a href="#">Item 6 Exhibits</a>	58
---------------------------------	----

<b><u>SIGNATURE PAGE</u></b>	59
------------------------------	----

[EX-12.1: STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO COMBINED FIXED CHARGES](#)

[EX-31.1: CERTIFICATION](#)

[EX-31.2: CERTIFICATION](#)

[EX-32: CERTIFICATION](#)

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[Table of Contents](#)**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****REGENERON PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS AT JUNE 30, 2007 AND DECEMBER 31, 2006 (Unaudited)***(In thousands, except share data)*

	June 30, 2007	December 31, 2006
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 109,643	\$ 237,876
Marketable securities	351,054	221,400
Accounts receivable	20,478	7,493
Prepaid expenses and other current assets	15,806	3,215
Total current assets	496,981	469,984
Restricted cash	1,600	1,600
Marketable securities	49,985	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	47,647	49,353
Other assets	1,645	2,170
Total assets	<u>\$ 597,858</u>	<u>\$ 585,090</u>
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 34,905	\$ 21,471
Deferred revenue, current portion	69,926	23,543
Total current liabilities	104,831	45,014
Deferred revenue	113,691	123,452
Notes payable	200,000	200,000
Total liabilities	<u>418,522</u>	<u>368,466</u>
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; shares issued and outstanding - 2,270,353 in 2007 and 2006	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 63,783,564 in 2007 and 63,130,962 in 2006	64	63
Additional paid-in capital	924,094	904,407
Accumulated deficit	(744,308)	(687,617)
Accumulated other comprehensive loss	(516)	(231)
Total stockholders' equity	179,336	216,624
Total liabilities and stockholders' equity	<u>\$ 597,858</u>	<u>\$ 585,090</u>

**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,	
	2007	2006	2007	2006
<b>Revenues</b>				
Contract research and development	\$ 15,917	\$ 14,991	\$ 29,562	\$ 29,578
Contract manufacturing		4,267		7,899
Technology licensing	6,278		8,421	
	<u>22,195</u>	<u>19,258</u>	<u>37,983</u>	<u>37,477</u>
<b>Expenses</b>				
Research and development	43,864	34,398	85,099	66,482
Contract manufacturing		2,810		4,662
General and administrative	8,935	6,299	17,137	12,245
	<u>52,799</u>	<u>43,507</u>	<u>102,236</u>	<u>83,389</u>
Loss from operations	<u>(30,604)</u>	<u>(24,249)</u>	<u>(64,253)</u>	<u>(45,912)</u>
<b>Other income (expense)</b>				
Investment income	6,841	3,684	13,584	7,165
Interest expense	<u>(3,011)</u>	<u>(3,011)</u>	<u>(6,022)</u>	<u>(6,022)</u>
	<u>3,830</u>	<u>673</u>	<u>7,562</u>	<u>1,143</u>
Net loss before cumulative effect of a change in accounting principle	(26,774)	(23,576)	(56,691)	(44,769)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")				813
Net loss	<u>\$ (26,774)</u>	<u>\$ (23,576)</u>	<u>\$ (56,691)</u>	<u>\$ (43,956)</u>
<b>Net loss per share amounts, basic and diluted:</b>				
Net loss before cumulative effect of a change in accounting principle	\$ (0.41)	\$ (0.41)	\$ (0.86)	\$ (0.79)
Cumulative effect of adopting SFAS 123R				0.02
Net loss	<u>\$ (0.41)</u>	<u>\$ (0.41)</u>	<u>\$ (0.86)</u>	<u>\$ (0.77)</u>
Weighted average shares outstanding, basic and diluted	65,950	56,915	65,757	56,821

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

[Table of Contents](#)

**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)**  
**For the six months ended June 30, 2007**  
**(In thousands)**

	Class A Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
<b>Balance, December 31, 2006</b>	<u>2,270</u>	<u>\$ 2</u>	<u>63,131</u>	<u>\$ 63</u>	<u>\$ 904,407</u>	<u>\$ (687,617)</u>	<u>\$ (231)</u>	<u>\$ 216,624</u>	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			588	1	4,823			4,824	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367			1,367	
Stock-based compensation expense					13,497			13,497	
Net loss						(56,691)		(56,691)	\$ (56,691)
Change in net unrealized loss on marketable securities							(285)	(285)	(285)
<b>Balance, June 30, 2007</b>	<u>2,270</u>	<u>\$ 2</u>	<u>63,784</u>	<u>\$ 64</u>	<u>\$ 924,094</u>	<u>\$ (744,308)</u>	<u>\$ (516)</u>	<u>\$ 179,336</u>	<u>\$ (56,976)</u>

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)**

	<u>Six months ended June 30,</u> <u>2007</u>	<u>2006</u>
Cash flows from operating activities		
Net loss	\$ (56,691)	\$ (43,956)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	5,729	7,488
Non-cash compensation expense	13,497	8,779
Cumulative effect of a change in accounting principle		(813)
Changes in assets and liabilities		
(Increase) decrease in accounts receivable	(12,985)	24,380
(Increase) decrease in prepaid expenses and other assets	(13,241)	627
Increase in inventory		1,279
Increase (decrease) in deferred revenue	36,622	(8,063)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	14,324	(5,118)
Total adjustments	<u>43,946</u>	<u>28,559</u>
Net cash used in operating activities	<u>(12,745)</u>	<u>(15,397)</u>
Cash flows from investing activities		
Purchases of marketable securities	(371,007)	(152,660)
Sales or maturities of marketable securities	253,719	95,292
Capital expenditures	(3,024)	(986)
Net cash used in investing activities	<u>(120,312)</u>	<u>(58,354)</u>
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	4,824	3,813
Other		390
Net cash provided by financing activities	<u>4,824</u>	<u>4,203</u>
Net decrease in cash and cash equivalents	(128,233)	(69,548)
Cash and cash equivalents at beginning of period	<u>237,876</u>	<u>184,508</u>
Cash and cash equivalents at end of period	<u>\$ 109,643</u>	<u>\$ 114,960</u>

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

[Table of Contents](#)**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, 2006 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, 2006.

**2. Per Share Data**

The Company’s basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2007 and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended June 30,	
	2007	2006
Net loss (Numerator)	\$(26,774)	\$(23,576)
Weighted-average shares, in thousands (Denominator)	65,950	56,915
Basic and diluted net loss per share	\$ (0.41)	\$ (0.41)
	Six Months Ended June 30,	
	2007	2006
Net loss (Numerator)	\$(56,691)	\$(43,956)
Weighted-average shares, in thousands (Denominator)	65,757	56,821
Basic and diluted net loss per share	\$ (0.86)	\$ (0.77)



[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the June 30, 2007 and 2006 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30,	
	2007	2006
<b>Stock Options:</b>		
Weighted average number, in thousands	15,228	14,181
Weighted average exercise price	\$ 15.91	\$ 14.32
<b>Restricted Stock:</b>		
Weighted average number, in thousands		40
<b>Convertible Debt:</b>		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25
	Six months ended June 30,	
	2007	2006
<b>Stock Options:</b>		
Weighted average number, in thousands	15,388	14,291
Weighted average exercise price	\$ 15.78	\$ 14.29
<b>Restricted Stock:</b>		
Weighted average number, in thousands		47
<b>Convertible Debt:</b>		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25

**3. Statement of Cash Flows**

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2007 and December 31, 2006 are \$1.3 million and \$0.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at both June 30, 2006 and December 31, 2005 are \$0.2 million of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2006 and 2005 are \$1.4 million and \$1.9 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2007 and 2006, the Company contributed 64,532 and 120,960

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at June 30, 2007 and December 31, 2006 are \$2.2 million and \$1.5 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2006 and December 31, 2005 are \$0.8 million and \$1.2 million, respectively, of accrued interest income.

**4. Accounts Receivable**

Accounts receivable as of June 30, 2007 and December 31, 2006 consist of the following:

	June 30, 2007	December 31, 2006
Receivable from the sanofi-aventis Group	\$ 11,410	\$ 6,900
Receivable from Bayer HealthCare LLC	7,463	
Other	1,605	593
	<u>\$ 20,478</u>	<u>\$ 7,493</u>

**5. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses as of June 30, 2007 and December 31, 2006 consist of the following:

	June 30, 2007	December 31, 2006
Accounts payable	\$ 18,546	\$ 4,349
Accrued payroll and related costs	7,222	9,932
Accrued clinical trial expense	4,316	2,606
Accrued expenses, other	2,529	2,292
Interest payable on convertible notes	2,292	2,292
	<u>\$ 34,905</u>	<u>\$ 21,471</u>

**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 (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and six months ended June 30, 2007 and 2006, the components of comprehensive loss are:

[Table of Contents](#)**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)*

	<u>Three months ended June 30,</u>	
	<u>2007</u>	<u>2006</u>
Net loss	\$ (26,774)	\$ (23,576)
Change in net unrealized gain (loss) on marketable securities	(357)	(102)
Total comprehensive loss	<u>\$ (27,131)</u>	<u>\$ (23,678)</u>

  

	<u>Six months ended June 30,</u>	
	<u>2007</u>	<u>2006</u>
Net loss	\$ (56,691)	\$ (43,956)
Change in net unrealized gain (loss) on marketable securities	(285)	(3)
Total comprehensive loss	<u>\$ (56,976)</u>	<u>\$ (43,959)</u>

**7. Accounting for Collaboration with Bayer HealthCare**

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of \$75.0 million. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$50.0 million will be shared equally; Regeneron is solely responsible for the next \$40.0 million; over \$90.0 million will be shared equally. Through June 30, 2007, reimbursements from Bayer HealthCare of the Company's VEGF Trap-Eye development expenses totaled \$10.6 million, of which \$7.5 million was receivable at June 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

The Company and Bayer HealthCare are currently formalizing the global development plans for the VEGF Trap-Eye in the collaboration's two initial eye disease indications. The plans will include estimated development steps, timelines and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. Pending completion of these plans, all payments received or receivable by the Company from Bayer HealthCare through June 30, 2007, totaling \$85.6 million, have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, the Company will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments (including the \$75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development expenses) will be recognized in the Company's Statement of Operations. In the period when the Company commences recognizing previously deferred payments from Bayer HealthCare, the Company anticipates recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements (Unaudited)**

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

**8. 2007 License Agreements**

***AstraZeneca***

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to the Company which was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. AstraZeneca also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's VelocImmune technology. For the six months ended June 30, 2007, the Company recognized \$7.1 million of revenue in connection with the AstraZeneca license agreement. At June 30, 2007, deferred revenue was \$12.9 million.

***Astellas***

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable up-front payment to the Company, which was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. Astellas also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. For the six months ended June 30, 2007, the Company recognized \$1.3 million of revenue in connection with the Astellas license agreement. At June 30, 2007, deferred revenue was \$18.7 million.

**9. Commitment — Purchase of Building**

In June 2007, the Company exercised a purchase option on a building in Rensselaer, New York, totaling approximately 270,000 square feet, in which the Company currently leases approximately 75,000 square feet of manufacturing, office, and warehouse space. The Company anticipates completing the purchase of this building in the third quarter of 2007 at a cost of approximately \$10 million.

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements (Unaudited)**

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

**10. Income Taxes**

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board (“FASB”) Interpretation No. 48 (“FIN 48”), *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company’s financial statements.

The Company is primarily subject to U.S. federal and New York State income tax. Tax years subsequent to 1991 remain open to examination by U.S. federal and state tax authorities.

The Company’s policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and June 30, 2007, the Company had no accruals for interest or penalties related to income tax matters.

**11. Legal Matters**

From time to time, the Company is a party to legal proceedings in the course of the Company’s business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company’s business or financial condition.

**12. Segment Information**

Through 2006, the Company’s operations were managed in two business segments: research and development, and contract manufacturing.

**Research and development:** Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to activities conducted under contract research and technology licensing agreements.

**Contract manufacturing:** Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006, the Company produced a vaccine intermediate for Merck & Co., Inc. under a manufacturing agreement, which expired in October 2006.

Due to the expiration of the Company’s manufacturing agreement with Merck in October 2006, beginning in 2007, the Company only has a research and development business segment. Therefore, segment information has not been provided for 2007 in the table below.

The following table presents information about reported segments for the three and six months ended June 30, 2006.

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements (Unaudited)**

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

	Three months ended June 30, 2006			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 14,991	\$4,267	—	\$ 19,258
Depreciation and amortization	3,429	—(1)	\$ 261	3,690
Non-cash compensation expense	4,603	97	—	4,700
Interest expense	—	—	3,011	3,011
Net (loss) income	(25,706)	1,457	673(2)	(23,576)
Capital expenditures	323	—	—	323

	Six months ended June 30, 2006			Total
	Research & Development	Contract Manufacturing	Reconciling Items	
Revenues	\$ 29,578	\$7,899	—	\$ 37,477
Depreciation and amortization	6,966	—(1)	\$ 522	7,488
Non-cash compensation expense	8,587	192	(813)(4)	7,966
Interest expense	—	—	6,022	6,022
Net (loss) income	(49,149)	3,237	1,956(2)	(43,956)
Capital expenditures	968	—	—	968
Total assets	64,543	3,580	310,209(3)	378,332

- (1) Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.
- (2) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the six months ended June 30, 2006, also includes the cumulative effect of adopting Statement of Financial Accounting Standards No. (“SFAS”) 123R, *Share-Based Payment*.
- (3) Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.
- (4) Represents the cumulative effect of adopting SFAS 123R.

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

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company will be required to adopt SFAS 159 effective

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements (Unaudited)**

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

for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 159 on the Company's financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company will be required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Management believes that the future adoption of EITF 07-3 will not have a material impact on the Company's financial statements.

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

*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.*

### Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: rilonacept (IL-1 Trap) in various inflammatory indications, the VEGF Trap (aflibercept) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal 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.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (VelocImmune<sup>®</sup>) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the VelocImmune platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move our first new antibody product candidate into clinical trials in the fourth quarter of 2007. We plan to introduce two new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.



**Clinical Programs:**

Below is a summary of the status of our clinical candidates as of June 30, 2007:

**1. Rilonacept — Inflammatory Diseases**

Rilonacept (IL-1 Trap) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating rilonacept in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

We recently submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for rilonacept in CAPS. The FDA has previously granted Orphan Drug status and Fast Track designation to rilonacept for the treatment of CAPS. In July 2007, rilonacept also received Orphan Drug designation in the European Union for the treatment of CAPS.

In October 2006, we announced positive data from our Phase 3 clinical trial, which was designed to provide two separate demonstrations of efficacy for rilonacept within a single group of adult patients suffering from CAPS. This Phase 3 trial included two studies (Part A and Part B). Both studies met their primary endpoints (Part A:  $p < 0.0001$  and Part B:  $p < 0.001$ ). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive rilonacept had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ( $p < 0.0001$ ). Following a 9-week interval during which all patients received rilonacept, a “randomized withdrawal” study (Part B) was performed, in which the patients in Part A were re-randomized to either switch to placebo or continue treatment with rilonacept in a double-blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on rilonacept who had no significant change ( $p < 0.001$ ). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on rilonacept than on placebo. In these studies, rilonacept appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. See Item 1A, “Risk Factors” under “Risks Related to Development of Our Product Candidates.”

## [Table of Contents](#)

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of rilonacept in other indications in which IL-1 may play a role. We are completing an exploratory proof of concept study of rilonacept in ten patients with chronic gout, and plan to begin a safety and efficacy study of rilonacept in gout patients in the third quarter of 2007. We are also preparing to initiate exploratory proof of concept studies of rilonacept in other indications, the first of which is planned to begin in the fourth quarter of 2007.

Under a 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. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation rilonacept following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our rilonacept currently in clinical development.

## **2. VEGF Trap — Oncology**

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, 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-A (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.

The VEGF Trap (aflibercept) is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are preparing to initiate a large Phase 3 program that will evaluate the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in five different cancer types. The first trial is planned to begin in the third quarter of 2007. The Phase 3 trials are planned in the following indications:

## Table of Contents

- first-line metastatic hormone resistant prostate cancer in combination with Taxotere® (Aventis),
- first-line metastatic pancreatic cancer in combination with gemcitabine-based regimen,
- first-line gastric cancer in combination with Taxotere® (Aventis),
- second-line non-small cell lung cancer in combination with Taxotere® (Aventis), and
- second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan).

Currently, the collaboration is conducting Phase 2 single-agent studies in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the FDA granted Fast Track designation to the VEGF Trap for the treatment of SMA.

In June 2007, at the annual meeting of the American Society of Clinical Oncology (ASCO), we and sanofi-aventis announced interim results from the Phase 2 studies in AOC and NSCLA. The AOC study, selected for an oral presentation at ASCO, was an interim analysis of a Phase 2 randomized, double-blind, multi-center trial investigating two doses of the VEGF Trap used as a single agent in patients with recurrent platinum-resistant epithelial ovarian cancer. While the study remains blinded with regard to dose, the combined preliminary results of the two dose levels for 162 of a planned 200 patients demonstrated anti-tumor activity as evidenced by an 8.0% partial response rate and 77% achievement of stable disease at 4 weeks in heavily pre-treated patients who had failed multiple other treatments. The VEGF Trap has been well tolerated, and the most common adverse events have been the typical class effect of anti-angiogenic agents. Of the 23 patients in the AOC study with evaluable baseline ascites, 7 patients (30%) experienced complete disappearance of the ascites, and 13 patients (57%) experienced no increase in ascites during treatment. The AOC study is ongoing and is now fully enrolled.

The NSCLA study, presented as a poster at ASCO, is a Phase 2 single-arm study conducted in patients with platinum-resistant and erlotinib-resistant adenocarcinoma of the lung (a common type of non-small cell lung cancer). In this study, the preliminary results presented at ASCO demonstrated activity in this heavily pre-treated patient base, as evidenced by a 3.7% partial response rate and 63% of patients achieving stable disease. The VEGF Trap has been well-tolerated in this trial as well. This study is ongoing and is now fully enrolled.

Sanofi-aventis has indicated that a first registration submission to a regulatory agency for the VEGF Trap is possible as early as 2008.

In addition, eight clinical studies have begun in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP). We and sanofi-aventis are working to finalize plans with NCI/CTEP to conduct additional trials in different cancer types.

Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the planned Phase 3 clinical program. In addition, sanofi-aventis has initiated the first trial of the VEGF Trap in

Japan, a Phase 1 safety and tolerability study in combination with S-1 in patients with advanced solid malignancies.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (Genentech) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

#### **Collaboration with the sanofi-aventis Group**

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide 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 be obligated to 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 profits and Japan royalties, or at a faster rate at our option.

### 3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In the clinical development program for the VEGF Trap-Eye, we and Bayer HealthCare announced that we have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial will compare the VEGF Trap-Eye and Genentech, Inc.'s Lucentis<sup>®</sup> (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. This Phase 3 trial is evaluating dosing intervals of four and eight weeks for the VEGF Trap-Eye compared with ranibizumab dosing according to its label every four weeks. Regeneron and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD around the end of 2007.

In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), we and Bayer HealthCare reported positive interim data from a pre-planned interim analysis of the Phase 2 study in wet AMD. The Phase 2 trial is a 150 patient, 12 week, study that is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. In the interim data analysis, the VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns,  $p < 0.0001$ ). Mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters,  $p < 0.0001$ ). Moreover, patients in the dose groups that received only a single dose, on average, compared to baseline, demonstrated a decrease in excess retinal thickness ( $p < 0.0001$ ) and an increase in visual acuity ( $p = 0.012$ ) at 12 weeks. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. Detailed data from this interim analysis is scheduled for presentation at an upcoming scientific conference. All patients have now completed 12 weeks of treatment, and we and Bayer HealthCare expect to report the results at a scientific conference in the third quarter of 2007. We are also conducting a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in wet AMD.

We are also developing the VEGF Trap-Eye in DME. In May 2007, at the ARVO meeting, the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity. We expect to initiate a safety and efficacy study in DME in the second half of 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and

## [Table of Contents](#)

Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

### **Collaboration with Bayer HealthCare**

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare and can earn up to \$110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

### **General**

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2007, we had a cumulative loss of \$744.3 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur

## Table of Contents

substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and riloncept; advance new product candidates into clinical development from our existing research programs utilizing our technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and 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 on, among other factors, 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 events for 2007 and plans over the next 12 months are as follows:

<u>Clinical Program</u>	<u>2007 Events to Date</u>	<u>2007-8 Plans</u>
VEGF Trap - Oncology	<ul style="list-style-type: none"><li>• NCI/CTEP initiated eight Phase 2 studies of the VEGF Trap as a single agent</li><li>• Reported interim results from two Phase 2 single-agent trials - in advanced ovarian cancer and in non-small cell lung adenocarcinoma</li><li>• Initiated Japanese Phase 1 trial of VEGF Trap in combination with S-1 in patients with solid malignancies</li></ul>	<ul style="list-style-type: none"><li>• Sanofi-aventis to initiate three of five Phase 3 studies of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer indications</li><li>• NCI/CTEP to initiate additional new exploratory safety and efficacy studies</li></ul>
VEGF Trap-Eye (intravitreal injection)	<ul style="list-style-type: none"><li>• Reported positive interim results of Phase 2 trial in wet AMD</li><li>• Reported positive results in Phase 1 trial in DME</li><li>• Initiated first Phase 3 trial in wet AMD</li></ul>	<ul style="list-style-type: none"><li>• Report final results of Phase 2 trial in wet AMD</li><li>• Initiate second Phase 3 trial in wet AMD</li><li>• Initiate safety and efficacy trial in DME</li><li>• Explore additional eye disease indications</li></ul>

## [Table of Contents](#)

<u>Clinical Program</u>	<u>2007 Events to Date</u>	<u>2007-8 Plans</u>
Rilonacept (IL-1 Trap)	<ul style="list-style-type: none"><li>Completed the 24 week open-label safety extension phase of the Phase 3 trial in CAPS</li><li>Submitted BLA to the FDA for CAPS</li><li>Orphan Drug designation in CAPS granted in European Union</li></ul>	<ul style="list-style-type: none"><li>FDA acceptance of BLA submission for CAPS and establishment of target completion date for FDA review of BLA</li><li>Report results of exploratory proof of concept study in patients with chronic gout</li><li>Initiate safety and efficacy trial in gout</li><li>Evaluate rilonacept in other disease indications in which IL-1 may play an important role</li></ul>
VelocImmune®		<ul style="list-style-type: none"><li>Initiate first trial for antibody product candidate</li><li>Finalize plans to initiate clinical trials for two additional antibody candidates in 2008</li></ul>

## License Agreements

### ***AstraZeneca***

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to us. AstraZeneca also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune technology.

### ***Astellas***

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable up-front payment to us. Astellas also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune technology.

### **Accounting for Collaboration with Bayer HealthCare**

As described above, in October 2006 we entered into a VEGF Trap-Eye license and collaboration agreement with Bayer HealthCare. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of \$75.0 million. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$50.0 million will be shared equally;



## [Table of Contents](#)

Regeneron is solely responsible for the next \$40.0 million; over \$90.0 million will be shared equally. Through June 30, 2007, reimbursements from Bayer HealthCare of our VEGF Trap-Eye development expenses total \$10.6 million, of which \$7.5 million was receivable at June 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

We and Bayer HealthCare are currently formalizing our global development plans for the VEGF Trap-Eye in wet AMD and DME. The plans will include estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. Pending completion of these plans, all payments received or receivable from Bayer HealthCare through June 30, 2007, totaling \$85.6 million, have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, we will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments from Bayer (including the \$75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development expenses) will be recognized in our Statement of Operations. In the period when we commence recognizing previously deferred payments from Bayer HealthCare, we anticipate recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

## Results of Operations

### Three Months Ended June 30, 2007 and 2006

#### Net Loss:

Regeneron reported a net loss of \$26.8 million, or \$0.41 per share (basic and diluted), for the second quarter of 2007 compared to a net loss of \$23.6 million, or \$0.41 per share (basic and diluted), for the second quarter of 2006.

#### Revenues:

Revenues for the three months ended June 30, 2007 and 2006 consist of the following:

<i>(In millions)</i>	2007	2006	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 13.5	\$ 14.8	\$ (1.3)
Other	2.4	0.2	2.2
Total contract research & development revenue	15.9	15.0	0.9
Contract manufacturing revenue		4.3	(4.3)
Technology licensing revenue	6.3		6.3
Total revenue	<u>\$ 22.2</u>	<u>\$ 19.3</u>	<u>\$ 2.9</u>

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of

## [Table of Contents](#)

reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

### Sanofi-aventis Contract Research & Development Revenue (In millions)

	Three months ended June 30,	
	2007	2006
Regeneron expense reimbursement	\$ 11.3	\$ 11.8
Recognition of deferred revenue related to up-front payments	2.2	3.0
Total	<u>\$ 13.5</u>	<u>\$ 14.8</u>

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the second quarter of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the second quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of June 30, 2007, \$65.5 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$1.6 million recognized in connection with our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the second quarter of 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 was \$0.4 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. In the second quarter of 2007, we recognized \$6.3 million of technology licensing revenue related to these agreements.

### Expenses:

Total operating expenses increased to \$52.8 million in the second quarter of 2007 from \$43.5 million in the same period of 2006. Our average employee headcount in the second quarter of

## [Table of Contents](#)

2007 increased to 618 from 579 in the second quarter of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials later this year. Operating expenses in the second quarter of 2007 and 2006 include a total of \$6.9 million and \$4.6 million, respectively, of non-cash compensation expense related to employee stock option awards (Stock Option Expense), as detailed below:

<i>(In millions)</i>	For the three months ended June 30, 2007		
	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Expenses			
Research and development	\$ 39.9	\$ 4.0	\$ 43.9
General and administrative	6.0	2.9	8.9
Total operating expenses	\$ 45.9	\$ 6.9	\$ 52.8

<i>(In millions)</i>	For the three months ended June 30, 2006		
	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Expenses			
Research and development	\$ 31.8	\$ 2.6	\$ 34.4
Contract manufacturing	2.7	0.1	2.8
General and administrative	4.4	1.9	6.3
Total operating expenses	\$ 38.9	\$ 4.6	\$ 43.5

The increase in total Stock Option Expense in the second quarter of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

### *Research and Development Expenses:*

Research and development expenses increased to \$43.9 million in the second quarter of 2007 from \$34.4 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2007 and 2006:

<i>(In millions)</i>	Three months ended June 30,		
	2007	2006	Increase
Research and development expenses			
Payroll and benefits (1)	\$ 14.4	\$ 11.7	\$ 2.7
Clinical trial expenses	6.5	4.4	2.1
Clinical manufacturing costs (2)	11.5	9.1	2.4
Research and preclinical development costs	6.1	4.3	1.8
Occupancy and other operating costs	5.4	4.9	0.5
Total research and development	\$ 43.9	\$ 34.4	\$ 9.5

(1) Includes \$3.3 million and \$2.2 million of Stock Option Expense for the three months ended June 30, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million and \$0.4 million of Stock Option Expense for the three months ended June 30, 2007 and 2006, respectively.

## [Table of Contents](#)

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to the increase in employee headcount, as described above, and annual salary increases effective January 1, 2007. Clinical trial expenses increased due primarily to (i) higher costs related to our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD, (ii) start-up costs related to our upcoming Phase 3 study of the VEGF Trap-Eye in wet AMD, and (iii) higher riloncept costs. Clinical manufacturing costs increased primarily because capacity which had previously been dedicated to manufacture of a vaccine intermediate for Merck, and whose cost had been included with Contract Manufacturing Expenses in 2006, has now been designated for, and the related costs included in, clinical manufacturing. In addition, higher costs related to manufacturing riloncept and preclinical and clinical supplies of our first antibody drug candidate were partly offset by lower costs related to manufacturing VEGF Trap. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs. In addition, higher preclinical development costs related to VEGF Trap and VEGF Trap-Eye were partly offset by lower preclinical development costs related to riloncept.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

<i>(In millions)</i>	Three months ended June 30,		
	2007	2006	Increase (Decrease)
<b>Project Costs</b>			
VEGF Trap — Oncology	\$ 10.0	\$ 10.1	\$ (0.1)
VEGF Trap- Eye	8.4	4.1	4.3
Riloncept	8.1	7.4	0.7
Other research programs & unallocated costs	17.4	12.8	4.6
Total research and development expenses	<u>\$ 43.9</u>	<u>\$ 34.4</u>	<u>\$ 9.5</u>

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical

## Table of Contents

programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of rilonacept, VEGF Trap, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described below in Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows. We submitted a BLA for our rilonacept for the treatment of CAPS, a spectrum of rare genetic disorders, in the second quarter of 2007. We cannot predict whether or when the commercialization of rilonacept in CAPS will result in a material net cash inflow to the company.

### *Contract Manufacturing Expenses:*

Contract manufacturing expenses decreased in the second quarter of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

### *General and Administrative Expenses:*

General and administrative expenses increased to \$8.9 million in the second quarter of 2007 from \$6.3 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense due, in part, to increases in administrative headcount in 2007 to support our expanded research and development activities and annual salary increases effective January 1, 2007, (iii) higher recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) marketing research and related expenses incurred in 2007 in connection with our rilonacept and VEGF Trap-Eye programs.

## [Table of Contents](#)

### *Other Income and Expense:*

Investment income increased to \$6.8 million in the second quarter of 2007 from \$3.7 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was \$3.0 million in the second quarter of 2007 and 2006. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

### **Six Months Ended June 30, 2007 and 2006**

#### *Net Loss:*

Regeneron reported a net loss of \$56.7 million, or \$0.86 per share (basic and diluted), for the first half of 2007 compared to a net loss of \$44.0 million, or \$0.77 per share (basic and diluted), for the same period of 2006.

#### *Revenues:*

Revenues for the six months ended June 30, 2007 and 2006 consist of the following:

<i>(In millions)</i>	<u>2007</u>	<u>2006</u>	<u>Increase (Decrease)</u>
Contract research & development revenue			
The sanofi-aventis Group	\$ 25.3	\$ 28.7	\$ (3.4)
Other	4.3	0.9	3.4
Total contract research & development revenue	29.6	29.6	—
Contract manufacturing revenue		7.9	(7.9)
Technology licensing revenue	8.4		8.4
Total revenue	<u>\$ 38.0</u>	<u>\$ 37.5</u>	<u>\$ 0.5</u>

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with SAB 104 and EITF 00-21. We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

#### **Sanofi-aventis Contract Research & Development Revenue** *(In millions)*

	<u>Six months ended June 30, 2007</u>	<u>2006</u>
Regeneron expense reimbursement	\$ 20.8	\$ 22.6
Recognition of deferred revenue related to up-front payments	4.5	6.1
Total	<u>\$ 25.3</u>	<u>\$ 28.7</u>

## [Table of Contents](#)

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the first half of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the first quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of June 30, 2007, \$65.5 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$2.3 million recognized in the first half of 2007 related to our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the first six months of 2006 related to our long-term manufacturing agreement with Merck, which expired in October 2006. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 was \$0.8 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. In the first six months of 2007, we recognized \$8.4 million of technology licensing revenue related to these agreements.

### *Expenses:*

Total operating expenses increased to \$102.2 million in the first half of 2007 from \$83.4 million in the same period of 2006. Our average employee headcount in the first half of 2007 increased to 602 from 583 in the first half of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and riloncept and our plans to move our first antibody candidate into clinical trials later this year. Operating expenses for the first six months of 2007 and 2006 include a total of \$13.5 million and \$8.5 million, respectively, of Stock Option Expense, as detailed below:

*(In millions)*

<u>Expenses</u>	<u>For the six months ended June 30, 2007</u>		
	<u>Expenses before inclusion of Stock Option Expense</u>	<u>Stock Option Expense</u>	<u>Expenses as Reported</u>
Research and development	\$ 77.2	\$ 7.9	\$ 85.1
General and administrative	11.5	5.6	17.1
Total operating expenses	<u>\$ 88.7</u>	<u>\$ 13.5</u>	<u>\$ 102.2</u>

## [Table of Contents](#)

(In millions)

Expenses	For the six months ended June 30, 2006		
	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	\$ 61.9	\$ 4.6	\$ 66.5
Contract manufacturing	4.5	0.2	4.7
General and administrative	8.5	3.7	12.2
Total operating expenses	<u>\$ 74.9</u>	<u>\$ 8.5</u>	<u>\$ 83.4</u>

The increase in total Stock Option Expense in the first half of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

### Research and Development Expenses:

Research and development expenses increased to \$85.1 million in the first half of 2007 from \$66.5 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2007 and 2006:

Research and development expenses	Six months ended June 30,		
	2007	2006	Increase
Payroll and benefits (1)	\$ 28.1	\$ 21.7	\$ 6.4
Clinical trial expenses	11.8	7.8	4.0
Clinical manufacturing costs (2)	22.0	18.4	3.6
Research and preclinical development costs	12.1	7.8	4.3
Occupancy and other operating costs	11.1	10.8	0.3
Total research and development	<u>\$ 85.1</u>	<u>\$ 66.5</u>	<u>\$ 18.6</u>

(1) Includes \$6.4 million and \$3.8 million of Stock Option Expense for the six months ended June 30, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.5 million and \$0.8 million of Stock Option Expense for the six months ended June 30, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to the increase in employee headcount, as described above, and annual salary increases effective January 1, 2007. Clinical trial expenses increased due primarily to (i) higher costs related to our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD, (ii) start-up costs related to our upcoming Phase 3 study of the VEGF Trap-Eye in wet AMD, and (iii) higher riloncept costs. Clinical manufacturing costs increased primarily because capacity which had previously been dedicated to manufacture of a vaccine intermediate for Merck, and whose cost had been included with Contract Manufacturing Expenses in 2006, has now been designated for, and the related costs included in, clinical manufacturing. Higher costs related to manufacturing riloncept and preclinical and clinical supplies of our first antibody drug candidate were offset by lower costs related to manufacturing VEGF Trap. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs. In addition, higher preclinical development



## [Table of Contents](#)

costs related to VEGF Trap-Eye and VEGF Trap-Oncology were partly offset by lower preclinical development costs related to rilonacept.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

<i>(In millions)</i>	Six months ended June 30,		
	2007	2006	Increase (Decrease)
<b>Project Costs</b>			
VEGF Trap — Oncology	\$ 17.8	\$ 19.2	\$ (1.4)
VEGF Trap- Eye	14.2	7.8	6.4
Rilonacept	15.9	14.3	1.6
Other research programs & unallocated costs	37.2	25.2	12.0
Total research and development expenses	<u>\$ 85.1</u>	<u>\$ 66.5</u>	<u>\$ 18.6</u>

For the reasons described above under “Research and Development Expenses” for the three months ended June 30, 2007 and 2006, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows.

### *Contract Manufacturing Expenses:*

Contract manufacturing expenses decreased in the first half of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

### *General and Administrative Expenses:*

General and administrative expenses increased to \$17.1 million in the first half of 2007 from \$12.2 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense due, in part, to increases in administrative headcount in 2007 to support our expanded research and development activities and annual salary increases effective January 1, 2007, (iii) higher recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) marketing research and related expenses incurred in 2007 in connection with our rilonacept and VEGF Trap-Eye programs.

### *Other Income and Expense:*

Investment income increased to \$13.6 million in the first half of 2007 from \$7.2 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities

## [Table of Contents](#)

(due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was \$6.0 million in first half of 2007 and 2006. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 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, payments earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

#### ***Six Months Ended June 30, 2007 and 2006***

At June 30, 2007, we had \$512.3 million in cash, cash equivalents, restricted cash, and marketable securities, compared with \$522.9 million at December 31, 2006. In connection with our new non-exclusive license agreements with AstraZeneca and Astellas, as described above, AstraZeneca and Astellas each made an up-front payment to us of \$20.0 million in February and April 2007, respectively.

#### ***Cash (Used in) Operations:***

Net cash used in operations was \$12.7 million in the first six months of 2007, compared to \$15.4 million in the first six months of 2006. Our net losses of \$56.7 million in the first half of 2007 and \$44.0 million in the first half of 2006 included \$13.5 million and \$8.8 million, respectively, of non-cash stock-based employee compensation costs, of which \$13.5 million and \$8.5 million, respectively, represented Stock Option Expense and, in the first half of 2006, \$0.3 million represented non-cash compensation expense from Restricted Stock awards. At June 30, 2007, accounts receivable balances increased by \$13.0 million, compared to year end 2006, primarily due to amounts receivable from sanofi-aventis and Bayer HealthCare for reimbursements of our VEGF Trap-Oncology and VEGF Trap-Eye development costs, respectively. Also, our deferred revenue balances at June 30, 2007 increased by \$36.6 million, compared to year end 2006, primarily due to the \$20.0 million up-front payments received from each of AstraZeneca and Astellas, as described above. In addition, for the first six months of 2007, reimbursements from Bayer HealthCare of our 2007 VEGF Trap-Eye development expenses, totaling \$10.6 million, have been fully deferred and included in deferred revenue for financial statement purposes, as discussed above. At June 30, 2006, accounts receivable balances decreased by \$24.4 million, compared to year end 2005, primarily due to the January 2006 receipt of a \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our collaboration agreement to include Japan. Also, our deferred revenue balances at June 30, 2006 decreased by \$8.1 million, compared to year end 2005, due primarily to first half 2006 revenue recognition of \$6.1 million of deferred revenue related to up-front payments from sanofi-aventis. The majority of our cash expenditures in both the first half of 2007 and 2006 were to fund research and development, primarily related to our clinical programs and, in the first half of 2007, our preclinical human monoclonal antibody programs.

## [Table of Contents](#)

### *Cash Used in Investing Activities:*

Net cash used in investing activities was \$120.3 million in the first half of 2007 compared to \$58.4 million in the same period of 2006, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first half of 2007, purchases of marketable securities exceeded sales or maturities by \$117.3 million, whereas in the first half of 2006, purchases of marketable securities exceeded sales or maturities by \$57.4 million.

### *Cash Provided by Financing Activities:*

Cash provided by financing activities increased to \$4.8 million in the first half of 2007 from \$4.2 million in the same period in 2006 due primarily to an increase in the issuance of Common Stock in connection with exercises of employee stock options.

### *License Agreements with AstraZeneca and Astellas:*

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a \$20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas also will each make up to five additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

### *Capital Expenditures:*

Our additions to property, plant, and equipment totaled \$3.5 million and \$1.0 million for the first half of 2007 and 2006, respectively. During the remainder of 2007, we expect to incur approximately \$13 million in capital expenditures primarily to support our manufacturing, development, and research activities.

During the second quarter of 2007, we exercised a purchase option on a building in Rensselaer, totaling approximately 270,000 square feet, in which we currently lease approximately 75,000 square feet of manufacturing, office and warehouse space. The acquisition of the building and related costs are expected to approximate \$10 million, which is included in our anticipated capital expenditures for the remainder of 2007, as described above. We expect to complete the purchase of this building in the third quarter of 2007. The space that we do not occupy in this building is currently leased to another tenant.

### *Convertible Debt:*

In 2001, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes, which bear interest at 5.5% per annum, payable semi-annually, and mature in October 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately \$30.25 per share, subject to adjustment in certain circumstances. If the price per share of our Common Stock is above \$30.25 at maturity, we would expect the notes to convert into shares of Common Stock. Otherwise, we will be required to repay the \$200.0

## [Table of Contents](#)

million aggregate principal amount of the notes or refinance the notes prior to maturity; however, we can provide no assurance that we will be able to successfully arrange such refinancing.

### **Funding Requirements:**

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2007 will be directed toward the preclinical and clinical development of product candidates, including riloncept, VEGF Trap, VEGF Trap-Eye and monoclonal antibodies; approximately 10%-15% of our expenditures for 2007 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2007 will be used for capital expenditures and general corporate purposes.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare are sharing agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as follows:

2007: Up to \$50.0 million shared equally; we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

In addition, under our collaboration agreements with sanofi-aventis and Bayer Healthcare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer Healthcare for 50% of agreed-upon development expenses incurred by sanofi-aventis and Bayer Healthcare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of the VEGF Trap-Oncology in collaboration with sanofi-aventis and the VEGF Trap-Eye in collaboration with Bayer Healthcare) such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer Healthcare will become profitable.

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 our collaborations with sanofi-aventis and Bayer HealthCare. 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,

## [Table of Contents](#)

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.

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 early 2010, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. 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. Other than the \$1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale back, or eliminate certain of our research and development activities or future operations. This could harm our business.

### **Critical Accounting Policies and Significant Judgments and Estimates**

#### *Revenue Recognition:*

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of

## Table of Contents

each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period. Payments for development activities where Regeneron is not sharing costs are recognized as revenue as earned, over the period of effort. In addition, we record revenue in connection with a government research grant as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if we and our collaborators decide to expand our clinical plans for a drug candidate into additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front payment at the time of the termination. For the year ended December 31, 2006, changes in estimates of our performance periods, including an extension of our estimated performance period for our collaboration with sanofi-aventis, did not have a material impact on contract research and development revenue that we recognized. In 2007, we currently expect to recognize at least \$2.4 million lower contract research and development revenue, compared to amounts recognized in 2006, in connection with \$105.0 million of non-refundable up-front payments previously received from sanofi-aventis, due to an extension of our estimated performance period.

As described above, we and Bayer HealthCare are currently formalizing our global development plans for the VEGF Trap-Eye in wet AMD and DME. Pending completion of these plans, all payments received or receivable from Bayer HealthCare through June 30, 2007 have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, we will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments from Bayer (including the \$75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development

## [Table of Contents](#)

expenses) will be recognized in our Statement of Operations. In the period when we commence recognizing previously deferred payments from Bayer HealthCare, we anticipate recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

### *Clinical Trial Expenses:*

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those with a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the year ended December 31, 2006 or the six months ended June 30, 2007.

## [Table of Contents](#)

During the three months ended June 30, 2007, there were no changes to any other “Critical Accounting Policies and Significant Judgments and Estimates” described in our Annual Report on Form 10-K for the year ended December 31, 2006.

### **Future Impact of Recently Issued Accounting Standards**

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. (SFAS) 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 159 on our financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We will be required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Our management believes that the future adoption of EITF 07-3 will not have a material impact on our financial statements.

### **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 approximately a \$2.0 million and \$0.9 million change in the fair market value of our investment portfolio at June 30, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at June 30, 2007, compared to June 30, 2006, is due primarily to increases in our investment portfolio’s balance and duration at the end of June 2007 versus June 2006.

### **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



## [Table of Contents](#)

end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us 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 June 30, 2007 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**

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

### **Item 1A. 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 in our Annual Report on Form 10-K for the year ended December 31, 2006 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 June 30, 2007, we had a cumulative loss of \$744.3 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 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 early 2010, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; 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.

### **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 payers and on 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

## [Table of Contents](#)

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.

We are studying our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and riloncept, in a wide variety of indications. We are studying the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and riloncept in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. 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 fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

***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 or comparator drug, 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 are studying higher doses of riloncept in different diseases after a Phase 2 trial using lower doses of riloncept 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 data from the Phase 3 clinical program for rilonacept in CAPS (Cryopyrin Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of rilonacept.***

We recently submitted a BLA to the FDA for rilonacept in CAPS. However, the efficacy and safety data from the Phase 3 clinical program included in the BLA may be inadequate to support approval for commercialization of rilonacept. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for rilonacept, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize rilonacept profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of rilonacept in those countries.

***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.

## [Table of Contents](#)

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in 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 systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic 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 or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test rilonacept in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen Inc.), Enbrel<sup>®</sup> (Immunex Corporation), and Remicade<sup>®</sup> (Centocor, Inc.), rilonacept affects the immune defense system of the body by blocking some of its functions. Therefore, rilonacept may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking rilonacept. One subject with adult Still's disease in a study of rilonacept developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymyalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of rilonacept in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of rilonacept have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of rilonacept.

***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 detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date — in some cases even after pivotal clinical trials have been completed. Of the clinical study subjects who received rilonacept for rheumatoid arthritis and other

## [Table of Contents](#)

indications, fewer than 5% of patients developed antibodies and no side effects related to antibodies were observed. Using a very sensitive test, approximately 40% of the patients in the CAPS pivotal study tested positive at least once for low levels of antibodies to rilonacept. Again, no side effects related to antibodies were observed and there were no observed effects on drug efficacy or drug levels. However, it is possible that as we continue to test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

***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. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. 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, VEGF Trap-Eye, and rilonacept, 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.

### **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 extremely expensive and time consuming.

***We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.***

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 products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our VelocImmune technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye 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 or VEGF Trap-Eye. 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 or VEGF Trap-Eye, 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 would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

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.

### **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

## [Table of Contents](#)

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.

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.

***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. 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.

***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.***



## [Table of Contents](#)

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 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, 2006, which report was included in our Annual Report on Form 10-K. 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. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

### **Risks Related to Our Dependence on Third Parties**

***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 oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide 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

## [Table of Contents](#)

develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would 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 substantial new and additional risks to the successful development of the VEGF Trap oncology program.

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

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States 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 outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

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

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, 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.***

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. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related 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

## [Table of Contents](#)

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 in cancer indications, 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, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

***Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and 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, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI 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. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, 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® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis® (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Biotechnology Ltd.), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize riloncept. This is one of the reasons we discontinued

the development of rilonacept in adult rheumatoid arthritis. In addition, even if rilonacept is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over rilonacept, such as requiring fewer injections.

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, Eli Lilly and Company and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. It has been reported that Novartis has commenced advanced clinical testing of its IL-1 antibody in Muckle-Wells Syndrome, which is part of the spectrum of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over rilonacept. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize rilonacept. For example, we may find it difficult to enroll patients in clinical trials for rilonacept if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing rilonacept for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS1* 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 rilonacept 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 payers and these payers may not agree to cover or reimburse for use of our products.***

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We are seeking approval to market rilonacept for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize rilonacept. Physicians may not prescribe rilonacept and CAPS patients may not be able to afford rilonacept if third party payers do not agree to reimburse the cost of rilonacept therapy and this would adversely affect our ability to commercialize rilonacept profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our

## [Table of Contents](#)

products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including rilonacept, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

### **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 certain of 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 P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. 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 Our Common Stock**

***Our stock price is extremely volatile.***

## Table of Contents

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 12, 2007, our seven largest shareholders beneficially owned 44.1% 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 12, 2007. As of April 12, 2007, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 4.4% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If 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, 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 generally 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 12, 2007, holders of Class A Stock held 26.4% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly



## Table of Contents

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 12, 2007:

- our current executive officers and directors beneficially owned 13.2% 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 12, 2007, and 30.4% 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 12, 2007; and
- our seven largest shareholders beneficially owned 44.1% 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 12, 2007. In addition, these seven shareholders held 51.0% 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 12, 2007.

***The anti-takeover effects of provisions of our charter, by-laws, 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 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

## Table of Contents

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.*”

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. 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 our company, as defined in the plan.

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

On June 8, 2007, 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 three Directors to hold office for a three-year term as Class I directors, and until their successors are duly elected and qualified.
2. To ratify the appointment of PricewaterhouseCoopers LLP as the Company’s independent registered public accounting firm for our fiscal year ending December 31, 2007.

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

	<u>For</u>	<u>Withheld</u>
1. Election of Class I Directors		
Leonard S. Schleifer, M.D., Ph.D.	78,309,187	1,546,154
Eric M. Shooter, Ph.D.	78,754,194	1,110,147
George D. Yancopoulos, M.D., Ph.D.	78,751,885	1,103,456

The terms of office of Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., P. Roy Vagelos, M.D., Charles A. Baker, Michael S. Brown, M.D., Arthur F. Ryan, and George L. Sing continued after the meeting.

	<u>For</u>	<u>Against</u>	<u>Abstain</u>
2. Ratification of the Appointment of Independent Registered Public Accounting Firm	79,244,209	217,182	393,949

[Table of Contents](#)

**Item 6. Exhibits**

(a) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
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: August 3, 2007

By: /s/ Murray A. Goldberg

Murray A. Goldberg  
Senior Vice President, Finance & Administration,  
Chief Financial Officer, Treasurer, and  
Assistant Secretary  
(Principal Financial Officer and  
Duly Authorized Officer)

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

	Years ended December 31,					Six months ended June 30, 2007
	2002	2003	2004	2005	2006	
<b>Earnings:</b>						
Income (loss) from continuing operations before income (loss) from equity investee	\$(124,350)	\$(107,395)	\$41,565	\$(95,456)	\$(103,150)	\$(56,691)
Fixed charges	13,685	14,108	14,060	13,687	13,643	6,854
Amortization of capitalized interest	—	33	78	78	73	12
Interest capitalized	(222)	(276)	—	—	—	—
<b>Adjusted earnings</b>	<b>\$(110,887)</b>	<b>\$ (93,530)</b>	<b>\$55,703</b>	<b>\$(81,691)</b>	<b>\$ (89,434)</b>	<b>\$(49,825)</b>
<b>Fixed charges:</b>						
Interest expense	\$ 11,859	\$ 11,932	\$12,175	\$ 12,046	\$ 12,043	\$ 6,022
Interest capitalized	222	276	—	—	—	—
Assumed interest component of rental charges	1,604	1,900	1,885	1,641	1,600	832
<b>Total fixed charges</b>	<b>\$ 13,685</b>	<b>\$ 14,108</b>	<b>\$14,060</b>	<b>\$ 13,687</b>	<b>\$ 13,643</b>	<b>\$ 6,854</b>
<b>Ratio of earnings to fixed charges</b>	<b>(A)</b>	<b>(A)</b>	<b>3.96</b>	<b>(A)</b>	<b>(A)</b>	<b>(A)</b>

(A) Due to the registrant's losses for the years ended December 31, 2002, 2003, 2005, and 2006, and for the six months ended June 30, 2007, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Six months ended June 30, 2007
	2002	2003	2005	2006	
Coverage deficiency	\$124,572	\$107,638	\$95,378	\$103,077	\$56,679

**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 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 (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: August 3, 2007

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

**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 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 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
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- 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: August 3, 2007

/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  
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 June 30, 2007 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

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Leonard S. Schleifer, M.D., Ph.D.  
Chief Executive Officer  
August 3, 2007

/s/ Murray A. Goldberg

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Murray A. Goldberg  
Chief Financial Officer  
August 3, 2007