

REGENERON PHARMACEUTICALS INC

Form 10-Q

November 07, 2007

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-Q**

(Mark One)

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

**For the quarterly period ended September 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

13-3444607

(State or other jurisdiction of incorporation or organization)

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

777 Old Saw Mill River Road  
Tarrytown, New York

10591-6707

(Address of principal executive offices)

(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

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

Yes  No

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 October 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	63,889,481



**REGENERON PHARMACEUTICALS, INC.**  
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**September 30, 2007**

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

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 97,416	\$ 237,876
Marketable securities	299,566	221,400
Accounts receivable	10,968	7,493
Prepaid expenses and other current assets	14,070	3,215
Total current assets	422,020	469,984
Restricted cash	1,600	1,600
Marketable securities	98,710	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	49,358	49,353
Other assets	1,408	2,170
Total assets	\$ 573,096	\$ 585,090
<b>LIABILITIES and STOCKHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 27,872	\$ 21,471
Deferred revenue, current portion	68,814	23,543
Total current liabilities	96,686	45,014
Deferred revenue	125,013	123,452
Notes payable	200,000	200,000
Total liabilities	421,699	368,466
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 - 2,260,266 in 2007 and 2,270,353 in 2006	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 63,825,329 in 2007 and 63,130,962 in 2006	64	63

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Additional paid-in capital	931,482	904,407
Accumulated deficit	(780,146)	(687,617)
Accumulated other comprehensive loss	(5)	(231)
Total stockholders' equity	151,397	216,624
Total liabilities and stockholders' equity	\$ 573,096	\$ 585,090

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

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

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Revenues				
Contract research and development	\$ 12,311	\$ 11,448	\$ 41,873	\$ 41,026
Contract manufacturing		4,176		12,075
Technology licensing	10,000		18,421	
	22,311	15,624	60,294	53,101
Expenses				
Research and development	51,689	34,808	136,788	101,290
Contract manufacturing		3,054		7,716
General and administrative	9,289	6,019	26,426	18,264
	60,978	43,881	163,214	127,270
Loss from operations	(38,667)	(28,257)	(102,920)	(74,169)
Other income (expense)				
Investment income	5,840	3,858	19,424	11,023
Interest expense	(3,011)	(3,011)	(9,033)	(9,033)
	2,829	847	10,391	1,990
Net loss before cumulative effect of a change in accounting principle	(35,838)	(27,410)	(92,529)	(72,179)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ( SFAS 123R )				813
Net loss	\$ (35,838)	\$ (27,410)	\$ (92,529)	\$ (71,366)
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	\$ (0.54)	\$ (0.48)	\$ (1.40)	\$ (1.27)
Cumulative effect of adopting SFAS 123R				0.02
Net loss	\$ (0.54)	\$ (0.48)	\$ (1.40)	\$ (1.25)

Weighted average shares outstanding, basic and diluted	66,069	57,011	65,861	56,884
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**The accompanying notes are an integral part of the financial statements.**

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

	Class A Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholder Equity	Accumulated Other Comprehensive Loss
	Shares	Amount	Shares	Amount					
<b>Balance, December 31, 2006</b>	2,270	\$ 2	63,131	\$ 63	\$ 904,407	\$ (687,617)	\$ (231)	\$ 216,624	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			619	1	5,170			5,171	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367			1,367	
Conversion of Class A Stock to Common Stock	(10)		10						
Stock-based compensation expense					20,538			20,538	
Net loss						(92,529)		(92,529)	\$ (92,529)
Change in net unrealized loss on marketable securities							226	226	226
<b>Balance, September 30, 2007</b>	2,260	\$ 2	63,825	\$ 64	\$ 931,482	\$ (780,146)	\$ (5)	\$ 151,397	\$ (92,303)

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

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

	<b>Nine months ended September</b>	
	<b>30,</b>	
	<b>2007</b>	<b>2006</b>
Cash flows from operating activities		
Net loss	\$ (92,529)	\$ (71,366)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	8,588	11,196
Non-cash compensation expense	20,538	13,542
Impairment charge on marketable securities	803	
Cumulative effect of a change in accounting principle		(813)
Changes in assets and liabilities		
(Increase) decrease in accounts receivable	(3,475)	28,581
(Increase) decrease in prepaid expenses and other assets	(11,876)	364
Decrease in inventory		3,524
Increase (decrease) in deferred revenue	46,832	(12,503)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	7,674	(2,753)
Total adjustments	69,084	41,138
Net cash used in operating activities	(23,445)	(30,228)
Cash flows from investing activities		
Purchases of marketable securities	(478,209)	(252,037)
Sales or maturities of marketable securities	363,739	261,749
Capital expenditures	(7,716)	(1,603)
Net cash (used in) provided by investing activities	(122,186)	8,109
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	5,171	4,883
Other		390
Net cash provided by financing activities	5,171	5,273
Net decrease in cash and cash equivalents	(140,460)	(16,846)
Cash and cash equivalents at beginning of period	237,876	184,508

Cash and cash equivalents at end of period	\$ 97,416	\$ 167,662
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**The accompanying notes are an integral part of the financial statements.**

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**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 nine months ended September 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 September 30,	
	2007	2006
Net loss (Numerator)	\$ (35,838)	\$ (27,410)
Weighted-average shares, in thousands (Denominator)	66,069	57,011
Basic and diluted net loss per share	\$ (0.54)	\$ (0.48)
	Nine Months Ended September 30,	
	2007	2006
Net loss (Numerator)	\$ (92,529)	\$ (71,366)
Weighted-average shares, in thousands (Denominator)	65,861	56,884
Basic and diluted net loss per share	\$ (1.40)	\$ (1.25)

**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 September 30, 2007 and 2006 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2007	2006
Stock Options:		
Weighted average number, in thousands	15,153	14,082
Weighted average exercise price	\$ 16.01	\$ 14.35
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25
	Nine months ended September 30,	
	2007	2006
Stock Options:		
Weighted average number, in thousands	15,308	14,220
Weighted average exercise price	\$ 15.86	\$ 14.31
Restricted Stock:		
Weighted average number, in thousands		31
Convertible Debt:		
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 September 30, 2007 and December 31, 2006 are \$0.9 million and \$0.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2006 and December 31, 2005 are \$0.4 million and \$0.2 million, respectively, 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 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

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

Included in marketable securities at September 30, 2007 and December 31, 2006 are \$2.5 million and \$1.5 million, respectively, of accrued interest income. Included in marketable securities at September 30, 2006 and December 31, 2005 are \$0.4 million and \$1.2 million, respectively, of accrued interest income.

**4. Accounts Receivable**

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

	September 30, 2007	December 31, 2006
Receivable from the sanofi-aventis Group	\$ 7,075	\$ 6,900
Receivable from National Institutes of Health	2,227	549
Receivable from Bayer HealthCare LLC	1,387	
Other	279	44
	\$ 10,968	\$ 7,493

**5. Accounts Payable and Accrued Expenses**

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

	September 30, 2007	December 31, 2006
Accounts payable	\$ 5,330	\$ 4,349
Accrued payroll and related costs	7,837	9,932
Accrued clinical trial expense	5,084	2,606
Accrued expenses, other	4,579	2,292
Interest payable on convertible notes	5,042	2,292
	\$ 27,872	\$ 21,471

**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 nine months ended September 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)*

	Three months ended September 30,	
	2007	2006
Net loss	\$ (35,838)	\$ (27,410)
Change in net unrealized gain (loss) on marketable securities	511	378
Total comprehensive loss	\$ (35,327)	\$ (27,032)

	Nine months ended September 30,	
	2007	2006
Net loss	\$ (92,529)	\$ (71,366)
Change in net unrealized gain (loss) on marketable securities	226	375
Total comprehensive loss	\$ (92,303)	\$ (70,991)

**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 September 30, 2007, reimbursements from Bayer HealthCare of the Company's VEGF Trap-Eye development expenses totaled \$12.9 million, of which \$1.4 million was receivable at September 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007. In addition, in August 2007, the Company received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration ( wet AMD ).

The Company and Bayer HealthCare are currently formalizing the global development plans for the VEGF Trap-Eye in wet AMD and diabetic macular edema. 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 September 30, 2007, totaling \$107.9 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 cannot be quantified at this time.

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**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*<sup>®</sup> 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 nine months ended September 30, 2007, the Company recognized \$12.1 million of revenue in connection with the AstraZeneca license agreement. At September 30, 2007, deferred revenue was \$7.9 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 nine months ended September 30, 2007, the Company recognized \$6.3 million of revenue in connection with the Astellas license agreement. At September 30, 2007, deferred revenue was \$13.7 million.

**9. 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



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**REGENERON PHARMACEUTICALS, INC.**

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

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

no impact on the Company's financial statements as the Company has no unrecognized tax benefits.

The Company is primarily subject to U.S. federal and New York State income tax. The Company's 1992 and subsequent tax years 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 September 30, 2007, the Company had no accruals for interest or penalties related to income tax matters.

**10. 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.

**11. 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 nine months ended September 30, 2006.

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

	Three months ended September 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 11,448	\$ 4,176		\$ 15,624
Depreciation and amortization	3,447	(1)	\$ 261	3,708
Non-cash compensation expense	4,632	130		4,762
Interest expense			3,011	3,011
Net (loss) income	(29,379)	1,122	847 <sup>(2)</sup>	(27,410)
Capital expenditures	441			441

	Nine months ended September 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	\$ 41,026	\$ 12,075		\$ 53,101
Depreciation and amortization	10,413	(1)	\$ 783	11,196
Non-cash compensation expense	13,220	322	(813) <sup>(3)</sup>	12,729
Interest expense			9,033	9,033
Net (loss) income	(78,528)	4,359	2,803 <sup>(2)</sup>	(71,366)
Capital expenditures	1,409			1,409
Total assets	57,530	1,445	296,211 <sup>(4)</sup>	355,186

(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 nine

months ended  
September 30,  
2006, also  
includes the  
cumulative  
effect of  
adopting  
Statement of  
Financial  
Accounting  
Standards No.  
( SFAS ) 123R,  
*Share-Based  
Payment.*

(3) Represents the  
cumulative  
effect of  
adopting SFAS  
123R.

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

## **12. 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

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**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.

**13. Subsequent Events**

***Purchase of Building Rensselaer, New York***

In June 2007, the Company exercised a purchase option on a building in Rensselaer, New York, in which the Company leased manufacturing, office, and warehouse space in a portion of the building. The Company completed the purchase of this property (land and building) in October 2007 at a cost of approximately \$9 million.

***Amendment to Operating Lease Tarrytown, New York Facilities***

The Company leases laboratory and office facilities in Tarrytown, New York. In December 2006, the Company entered into a new agreement to lease laboratory and office space that is now under construction and expected to be completed in mid-2009 at the Company's current Tarrytown location, plus retain a portion of the Company's existing space. In October 2007, the Company amended the December 2006 operating lease agreement to increase the amount of new space the Company will lease. The term of the lease is now expected to commence in mid-2008 and will expire approximately 16 years later. Other terms and conditions, as previously described in the Company's Form 10-K for the year ended December 31, 2006, remain unchanged.

In connection with these two subsequent events, the Company's previously disclosed total estimated future minimum noncancelable lease commitments under operating leases, as per the Company's Form 10-K for the year ended December 31, 2006, will decrease to \$4.6 million and \$9.3 million for the years ended December 31, 2008 and 2009, respectively, and increase to \$14.2 million and \$14.4 million for the years ended December 31, 2010 and 2011, respectively, and to \$204.2 million, in the aggregate, for years subsequent to 2011.

**Table of Contents****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, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept 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, beginning in 2008. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

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**Clinical Programs:**

Below is a summary of the status of our clinical candidates:

**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 group 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. In August 2007, the FDA granted priority review status to the BLA for rilonacept for the long-term treatment of CAPS. The FDA 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 November 2007, we announced that we received notification from the FDA that the action date for the FDA's priority review of the BLA for rilonacept had been extended three months to February 29, 2008.

CAPS represents a group of rare inherited auto-inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). CAPS also includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). Rilonacept has not been studied, and is not expected to be indicated, for the treatment of NOMID. The syndromes included in CAPS are characterized by spontaneous, systemic inflammation and are termed auto-inflammatory 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 is caused by a range of mutations in the gene *CIAS1* (also known as NLRP3) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We recently reported positive results from an exploratory proof of concept study of rilonacept in ten patients with chronic active gout. In those patients, treatment with rilonacept demonstrated a statistically significant reduction in patient pain scores in the single-blind, placebo-controlled study. Mean patients' pain scores, the key symptom measure in persistent gout, were reduced 41% ( $p=0.025$ ) during the first two weeks of active treatment and reduced 56% ( $p<0.004$ ) after six weeks of active treatment. In this study, in which safety was the primary endpoint measure, treatment with rilonacept was generally well-tolerated. We have initiated a Phase 2 safety and efficacy trial of rilonacept in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease.

We are also evaluating the potential use of rilonacept in other indications in which IL-1 may play a role, and are preparing to initiate exploratory proof-of-concept studies in anemia and other indications. The first of these studies will be in the treatment of anemia associated with chronic inflammation, which we plan to begin in the fourth quarter of 2007.

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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.

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. Aflibercept (VEGF Trap) Oncology**

Aflibercept 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.

Aflibercept is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis began the first two trials of our global Phase 3 development program in the third quarter of 2007. One trial will evaluate aflibercept in combination with docetaxel/prednisone in patients with 1<sup>st</sup> line metastatic androgen independent prostate cancer. The other trial will evaluate aflibercept in combination with docetaxel in patients with 2<sup>nd</sup> line metastatic non-small cell lung cancer. The companies plan to initiate two additional Phase 3 trials before the end of 2007 in first-line metastatic pancreatic cancer in combination with gemcitabine-based regimen and second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan). In all of these trials, aflibercept is being combined with the current standard of chemotherapy care for the stated development stage of the cancer type.

The collaboration is conducting a number of other trials in the global development program for aflibercept. Five safety and tolerability studies of aflibercept in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the Phase 3 clinical program. Sanofi-aventis has also expanded the development program to Japan, where they are conducting a Phase 1 safety and tolerability study in combination with S-1 in patients with advanced solid malignancies.

The collaboration is also 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). The AOC and NSCLA trials are fully enrolled and ongoing. The

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SMA trial is approximately 50% enrolled and continues to enroll patients. In 2004, the FDA granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, currently underway or scheduled to begin are more than 10 studies to be conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

The development program in oncology is expected to total over \$400 million over the next several years. These expenses will be funded by sanofi-aventis in accordance with the terms of our collaboration agreement described below.

The first registration submission to a regulatory agency for aflibercept is possible as early as 2008, potentially as third line treatment as a single agent in advanced ovarian cancer (AOC). However, in order for our ongoing Phase 2 study in AOC to be sufficient to support such a submission, we believe that the final unblinded results of the study would have to demonstrate a more robust response rate than that reported in the interim analysis of blinded data from the study presented in June 2007 at the annual meeting of the American Society of Clinical Oncology (ASCO).

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<sup>®</sup>. Avastin<sup>®</sup> (a trademark of Genentech, Inc.) 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 aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept 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 aflibercept 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 aflibercept outside of Japan for disease



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indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, 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 aflibercept 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 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 aflibercept 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 3 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and has completed 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 have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial, known as VIEW 1 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), is comparing 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 dosed according to its label every four weeks. We and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD in the first quarter of 2008. This second trial will be conducted primarily in the European Union and other parts of the world outside the U.S.

In October 2007, we and Bayer HealthCare announced positive results from the full analysis of the primary 12-week endpoint of a Phase 2 study evaluating the VEGF Trap-Eye in wet AMD. The VEGF Trap-Eye met the primary study endpoint of a statistically significant reduction in retinal thickness, a measure of disease activity, after 12 weeks of treatment compared with baseline (all five dose groups combined, mean decrease of 119 microns,  $p < 0.0001$ ). The mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.7 letters,  $p < 0.0001$ ). Preliminary analyses at 16 weeks showed that the VEGF Trap-Eye, dosed monthly, achieved a mean gain in visual acuity of 9.3 to 10 letters (for the 0.5 and 2 mg dose groups, respectively). In additional exploratory analyses, the VEGF Trap-Eye, dosed monthly, reduced the proportion of patients with vision of 20/200 or worse (a generally accepted definition for legal blindness) from 14.3% at baseline to 1.6% at week 16; the proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) was likewise increased from 19.0% at baseline to 49.2% at 16 weeks. These findings were presented at the Retina Society Conference.

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We and Bayer HealthCare are also developing the VEGF Trap-Eye in DME and expect to initiate a Phase 3 study in DME in mid-2008. In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap-Eye was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity.

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 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 LLC**

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. Bayer HealthCare will market the VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of the VEGF Trap-Eye. 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. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in wet AMD, and can earn up to \$90.0 million in additional 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.

**Table of Contents****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 September 30, 2007, we had a cumulative loss of \$780.1 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 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:

<b>Clinical Program</b>	<b>2007 Events to Date</b>	<b>2007-8 Plans</b>
Riloncept (IL-1 Trap)	<p>Completed the 24-week open-label safety extension phase of the Phase 3 trial in CAPS</p> <p>FDA accepted BLA submission for CAPS</p> <p>Granted Orphan Drug designation in CAPS in European Union</p> <p>Reported positive results in exploratory proof-of-concept study in patients with chronic active gout</p> <p>Initiated Phase 2 trial evaluating safety and efficacy of riloncept in preventing gout-induced flares in patients initiating allopurinol therapy</p>	<p>Receive FDA review decision to BLA submission for CAPS (expected in February 2008)</p> <p>Initiate exploratory proof-of- concept study of riloncept in a new indication</p> <p>Evaluate riloncept in other disease indications in which IL-1 may play an important role</p>

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**Clinical Program**

Aflibercept (VEGF Trap)  
Oncology

**2007 Events to Date**

NCI/CTEP initiated more than 10 studies of the aflibercept as a single agent  
 Reported interim results from two Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung adenocarcinoma  
 Initiated Japanese Phase 1 trial of aflibercept in combination with S-1 in patients with solid malignancies  
 Sanofi-aventis initiated two Phase 3 trials of aflibercept in combination with standard chemotherapy regimens

**2007-8 Plans**

Sanofi-aventis to initiate two additional Phase 3 studies of aflibercept in combination with standard chemotherapy regimens in specific cancer indications  
 NCI/CTEP to initiate additional new exploratory safety and efficacy studies

VEGF Trap-Eye  
(intravitreal injection)

Initiated first Phase 3 trial in wet AMD in patients in the U.S. and Canada  
 Reported positive primary endpoint results and preliminary extended treatment results of Phase 2 trial in wet AMD  
 Reported positive results in Phase 1 trial in DME

Initiate second Phase 3 trial in wet AMD in the European Union and other countries around the world  
 Initiate Phase 3 trial in DME  
 Explore additional eye disease indications

*VelocImmune*<sup>®</sup>

Initiate first trial for antibody product candidate  
 Finalize plans to initiate clinical trials for two additional antibody candidates in 2008

**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*<sup>®</sup> 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.

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***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 August 2007, we received a \$20.0 million development milestone payment from Bayer HealthCare, as described above. 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 September 30, 2007, reimbursements from Bayer HealthCare of our VEGF Trap-Eye development expenses total \$12.9 million, of which \$1.4 million was receivable at September 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 September 30, 2007, totaling \$107.9 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 cannot be quantified at this time.

**Table of Contents****Results of Operations****Three Months Ended September 30, 2007 and 2006***Net Loss:*

Regeneron reported a net loss of \$35.8 million, or \$0.54 per share (basic and diluted), for the third quarter of 2007 compared to a net loss of \$27.4 million, or \$0.48 per share (basic and diluted), for the third quarter of 2006.

*Revenues:*

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

<i>(In millions)</i>	<b>2007</b>	<b>2006</b>	<b>Increase (Decrease)</b>
Contract research & development revenue			
The sanofi-aventis Group	\$ 9.2	\$ 10.0	\$ (0.8)
Other	3.1	1.4	1.7
Total contract research & development revenue	12.3	11.4	0.9
Contract manufacturing revenue		4.2	(4.2)
Technology licensing revenue	10.0		10.0
Total revenue	\$ 22.3	\$ 15.6	\$ 6.7

We recognize revenue from sanofi-aventis, in connection with the companies' aflibercept collaboration, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issues 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 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.

<b>Sanofi-aventis Contract Research &amp; Development Revenue</b>	<b>Three months ended September</b>	
<i>(In millions)</i>	<b>2007</b>	<b>2006</b>
Regeneron expense reimbursement	\$ 7.0	\$ 7.0
Recognition of deferred revenue related to up-front payments	2.2	3.0
Total	\$ 9.2	\$ 10.0

Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the third 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 September 30, 2007, \$63.2 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 \$2.2 million and \$0.1 million in the third quarters of 2007 and 2006, respectively, 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 third 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



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expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the third 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 third quarter of 2007, we recognized \$10.0 million of technology licensing revenue related to these agreements.

*Expenses:*

Total operating expenses increased to \$61.0 million in the third quarter of 2007 from \$43.9 million in the same period of 2006. Our average employee headcount in the third quarter of 2007 increased to 639 from 557 in the third quarter 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. Operating expenses in the third quarter of 2007 and 2006 include a total of \$7.0 million and \$4.7 million, respectively, of non-cash compensation expense related to employee stock option awards (Stock Option Expense), as detailed below:

	<b>For the three months ended September 30, 2007</b>		
<i>(In millions)</i>	<b>Expenses before inclusion of Stock Option Expense</b>	<b>Stock Option Expense</b>	<b>Expenses as Reported</b>
Expenses			
Research and development	\$ 47.6	\$ 4.1	\$ 51.7
General and administrative	6.4	2.9	9.3
Total operating expenses	\$ 54.0	\$ 7.0	\$ 61.0

	<b>For the three months ended September 30, 2006</b>		
<i>(In millions)</i>	<b>Expenses before inclusion of Stock Option Expense</b>	<b>Stock Option Expense</b>	<b>Expenses as Reported</b>
Expenses			
Research and development	\$ 32.1	\$ 2.7	\$ 34.8
Contract manufacturing	3.0	0.1	3.1
General and administrative	4.1	1.9	6.0
Total operating expenses	\$ 39.2	\$ 4.7	\$ 43.9

The increase in total Stock Option Expense in the third 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 \$51.7 million in the third quarter of 2007 from \$34.8 million in the same period of 2006. The following table summarizes the major

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categories of our research and development expenses for the three months ended September 30, 2007 and 2006:

<i>(In millions)</i>	<b>Three months ended September 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>Increase</b>
<b>Research and development expenses</b>			
Payroll and benefits (1)	\$ 15.2	\$ 11.0	\$ 4.2
Clinical trial expenses	12.9	3.1	9.8
Clinical manufacturing costs (2)	11.9	10.0	1.9
Research and preclinical development costs	5.8	5.5	0.3
Occupancy and other operating costs	5.9	5.2	0.7
 Total research and development	 \$ 51.7	 \$ 34.8	 \$ 16.9

(1) Includes \$3.4 million and \$2.3 million of Stock Option Expense for the three months ended September 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 \$0.5 million of

Stock Option  
Expense for the  
three months  
ended  
September 30,  
2007 and 2006,  
respectively.

Payroll and benefits increased primarily due to higher compensation expense due, in part, to the increase in employee headcount, as described above and annual salary increases effective January 1, 2007, and higher Stock Option Expense, as described above. 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) costs related to our Phase 3 study of the VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and (iii) higher riloncept costs. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing riloncept and preclinical and clinical supplies of our first antibody drug candidate. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs and utilization of our proprietary technology platforms, such as for our NIH grant, as described above. Occupancy and other operating costs increased primarily as a result of higher facility-related and maintenance costs.

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>	<b>Three months ended September 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>Increase (Decrease)</b>
<b>Project Costs</b>			
Riloncept	\$ 12.9	\$ 7.7	\$ 5.2
Aflibercept (VEGF Trap) Oncology	5.5	5.5	
VEGF Trap- Eye	14.1	5.8	8.3
Other research programs & unallocated costs	19.2	15.8	3.4
Total research and development expenses	\$ 51.7	\$ 34.8	\$ 16.9

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

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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 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 riloncept, aflibercept, and the 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. In the second quarter of 2007, we submitted a BLA for our riloncept for the treatment of CAPS, a group of rare genetic disorders. We cannot predict whether or when the commercialization of riloncept in CAPS will result in a material net cash inflow to us.

*Contract Manufacturing Expenses:*

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

**Table of Contents***General and Administrative Expenses:*

General and administrative expenses increased to \$9.3 million in the third quarter of 2007 from \$6.0 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, (v) marketing research and related expenses incurred in 2007 in connection with our riloncept and VEGF Trap-Eye programs, and (vi) higher administrative facility and occupancy costs.

*Other Income and Expense:*

Investment income increased to \$5.8 million in the third quarter of 2007 from \$3.9 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). This increase was partly offset by a \$0.8 million charge in the third quarter of 2007 related to marketable securities which we considered to be other than temporarily impaired. Interest expense was \$3.0 million in the third 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.

***Nine Months Ended September 30, 2007 and 2006****Net Loss:*

Regeneron reported a net loss of \$92.5 million, or \$1.40 per share (basic and diluted), for the first nine months of 2007 compared to a net loss of \$71.4 million, or \$1.25 per share (basic and diluted), for the same period of 2006.

*Revenues:*

Revenues for the nine months ended September 30, 2007 and 2006 consist of the following:

<i>(In millions)</i>	<b>2007</b>	<b>2006</b>	<b>Increase (Decrease)</b>
Contract research & development revenue			
The sanofi-aventis Group	\$ 34.5	\$ 38.7	\$ (4.2)
Other	7.4	2.3	5.1
Total contract research & development revenue	41.9	41.0	0.9
Contract manufacturing revenue		12.1	(12.1)
Technology licensing revenue	18.4		18.4
Total revenue	\$ 60.3	\$ 53.1	\$ 7.2

We recognize revenue from sanofi-aventis, in connection with the companies aflibercept 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

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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.

<b>Sanofi-aventis Contract Research &amp; Development Revenue</b> <i>(In millions)</i>	<b>Nine months ended September</b>	
	<b>2007</b>	<b>30, 2006</b>
Regeneron expense reimbursement	\$ 27.8	\$ 29.6
Recognition of deferred revenue related to up-front payments	6.7	9.1
<b>Total</b>	<b>\$ 34.5</b>	<b>\$ 38.7</b>

Sanofi-aventis reimbursement of Regeneron aflibercept expenses decreased in the first nine months of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis up-front payments decreased for the first nine months 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 September 30, 2007, \$63.2 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 \$4.5 million and \$0.1 million for the first nine months of 2007 and 2006, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the first nine 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 third quarter of 2006 was \$1.2 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 nine months of 2007, we recognized \$18.4 million of technology licensing revenue related to these agreements.

*Expenses:*

Total operating expenses increased to \$163.2 million in the first nine months of 2007 from \$127.3 million in the same period of 2006. Our average employee headcount in the first nine months of 2007 increased to 614 from 574 in the first nine months of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and riloncept and our plans to

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move our first antibody candidate into clinical trials. Operating expenses for the first nine months of 2007 and 2006 include a total of \$20.5 million and \$13.2 million, respectively, of Stock Option Expense, as detailed below:

<i>(In millions)</i>	<b>For the nine months ended September 30, 2007</b>		
	<b>Expenses before inclusion of Stock Option Expense</b>	<b>Stock Option Expense</b>	<b>Expenses as Reported</b>
Research and development	\$ 124.8	\$ 12.0	\$ 136.8
General and administrative	17.9	8.5	26.4
Total operating expenses	\$ 142.7	\$ 20.5	\$ 163.2

<i>(In millions)</i>	<b>For the nine months ended September 30, 2006</b>		
	<b>Expenses before inclusion of Stock Option Expense</b>	<b>Stock Option Expense</b>	<b>Expenses as Reported</b>
Research and development	\$ 94.0	\$ 7.3	\$ 101.3
Contract manufacturing	7.4	0.3	7.7
General and administrative	12.7	5.6	18.3
Total operating expenses	\$ 114.1	\$ 13.2	\$ 127.3

The increase in total Stock Option Expense in the first nine months 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 \$136.8 million in the first nine months of 2007 from \$101.3 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2007 and 2006:

<i>(In millions)</i>	<b>Nine months ended September 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>Increase</b>
<b>Research and development expenses</b>			
Payroll and benefits (1)	\$ 43.3	\$ 32.7	\$ 10.6
Clinical trial expenses	24.8	11.0	13.8
Clinical manufacturing costs (2)	33.8	28.3	5.5
Research and preclinical development costs	17.9	13.3	4.6
Occupancy and other operating costs	17.0	16.0	1.0
Total research and development	\$ 136.8	\$ 101.3	\$ 35.5

- (1) Includes \$9.8 million and \$6.1 million of Stock Option Expense for the nine months ended September 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 \$2.2 million and \$1.2 million of Stock Option Expense for the nine months ended September 30, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher compensation expense due, in part, to the increase in employee headcount, as described above and annual salary increases effective January 1, 2007, and higher Stock Option Expense, as described above. Clinical trial expenses



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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) costs related to our Phase 3 study of the VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and (iii) higher riloncept costs. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing riloncept and preclinical and clinical supplies of our first antibody drug candidate, which 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 and utilization of our proprietary technology platforms, such as for our NIH grant, as described above. Occupancy and other operating costs increased primarily as a result of higher facility-related and maintenance costs.

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>	<b>Nine months ended September 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>Increase (Decrease)</b>
<b>Project Costs</b>			
Riloncept	\$ 28.7	\$ 22.0	\$ 6.7
Aflibercept (VEGF Trap) Oncology	23.3	24.8	(1.5)
VEGF Trap- Eye	28.3	13.7	14.6
Other research programs & unallocated costs	56.5	40.8	15.7
Total research and development expenses	\$ 136.8	\$ 101.3	\$ 35.5

For the reasons described above under **Research and Development Expenses** for the three months ended September 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 nine months 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 \$26.4 million in the first nine months of 2007 from \$18.3 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

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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 riloncept and VEGF Trap-Eye programs.

*Other Income and Expense:*

Investment income increased to \$19.4 million in the first nine months of 2007 from \$11.0 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). This increase was partly offset by a \$0.8 million charge in the first nine months of 2007 related to marketable securities which, during the third quarter of 2007, we considered to be other than temporarily impaired. Interest expense was \$9.0 million in first nine months 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.

***Nine Months Ended September 30, 2007 and 2006***

At September 30, 2007, we had \$497.3 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. In the third quarter of 2007, the Company received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in wet AMD.

*Cash Used in Operations:*

Net cash used in operations was \$23.4 million in the first nine months of 2007, compared to \$30.2 million in the first nine months of 2006. Our net losses of \$92.5 million in the first nine months of 2007 and \$71.4 million in the first nine months of 2006 included \$20.5 million and \$13.5 million, respectively, of non-cash stock-based employee compensation costs, of which \$20.5 million and \$13.2 million, respectively, represented Stock Option Expense and, in the first nine months of 2006, \$0.3 million represented non-cash compensation expense from Restricted Stock awards. At September 30, 2007, our deferred revenue balances increased by \$46.8 million, compared to year end 2006, due, in part, to the unrecognized balances of the two \$20.0 million up-front payments received from each of AstraZeneca and Astellas, as described above. In addition, for the first nine months of 2007, the \$20.0 million development milestone payment received from Bayer HealthCare in August 2007 and reimbursements from Bayer HealthCare of our 2007 VEGF Trap-Eye development expenses, totaling \$12.9 million, have been fully

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deferred and included in deferred revenue for financial statement purposes, as discussed above. At September 30, 2006, accounts receivable balances decreased by \$28.6 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 September 30, 2006 decreased by \$12.5 million, compared to year end 2005, due primarily to the revenue recognition of \$9.1 million of deferred revenue related to up-front payments from sanofi-aventis during the first nine months of 2006. The majority of our cash expenditures in both the first nine months of 2007 and 2006 were to fund research and development, primarily related to our clinical programs and, in the first nine months of 2007, our preclinical human monoclonal antibody programs.

***Cash (Used in) Provided by Investing Activities:***

Net cash used in investing activities was \$122.2 million in the first nine months of 2007 compared to net cash provided by investing activities of \$8.1 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 nine months of 2007, purchases of marketable securities exceeded sales or maturities by \$114.5 million, whereas in the first nine months of 2006, sales or maturities of marketable securities exceeded purchases by \$9.7 million.

***Cash Provided by Financing Activities:***

Cash provided by financing activities, which in the first nine months of 2007 and 2006 is attributable primarily to the issuance of Common Stock in connection with exercises of employee stock options, decreased slightly to \$5.2 million in the first nine months of 2007 from \$5.3 million in the same period in 2006.

***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 \$7.9 million and \$1.8 million for the first nine months of 2007 and 2006, respectively. During the remainder of 2007, we expect to incur approximately \$10-12 million in capital expenditures (including approximately \$9 million to purchase a facility in Rensselaer, New York, as described below) 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 leased approximately 75,000 square feet of manufacturing, office and warehouse space. We completed the purchase of

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this property (land and building) in October 2007 at a cost of approximately \$9 million, which is included in our anticipated capital expenditures for the remainder of 2007, as described above. 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 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.

***Amendment to Operating Lease Tarrytown, New York Facilities:***

We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new lease agreement to lease approximately 221,000 square feet of laboratory and office space at our current Tarrytown location, which includes approximately 27,000 square feet that would be retained from our current space and approximately 194,000 square feet in new facilities that are currently under construction and expected to be completed in mid-2009. In October 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of 257,000 square feet. The term of the lease is now expected to commence in mid-2008 and will expire approximately 16 years later. Other terms and conditions, as previously described in our Form 10-K for the year ended December 31, 2006, remain unchanged.

***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 rilonacept, aflibercept, 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.

In connection with the amendment to our new operating lease agreement on our Tarrytown facilities and the purchase of a building in Rensselaer where we leased manufacturing, warehouse and office space, each as described above, our previously disclosed funding requirements for operating leases, as per our Form 10-K for the year ended December 31, 2006, will decrease for the two-year period beginning January 1, 2008 from \$15.6 million to \$13.9

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million, increase for the two-year period beginning January 1, 2010 from \$24.0 million to \$28.6 million, and increase, in the aggregate, for fiscal years beginning January 1, 2012 and thereafter from \$161.4 million to \$204.2 million.

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.

Through September 30, 2007, cumulative shared development expenses have exceeded \$50.0 million.

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 aflibercept 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, 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.

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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 a \$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 September 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 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

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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 September 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 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 cannot be quantified at this time.

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*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 nine months ended September 30, 2007.

During the three months ended September 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.



**Table of Contents****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***Interest Rate 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, asset-backed, and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would result in approximately a \$2.2 million and \$0.5 million decrease in the fair market value of our investment portfolio at September 30, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at September 30, 2007, compared to September 30, 2006, is due primarily to increases in our investment portfolio's balance and duration at the end of September 2007 versus September 2006.

*Credit Quality Risk:*

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In the third quarter of 2007, we recognized a \$0.8 million charge related to securities that we considered to be other than temporarily impaired.

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**Item 4. Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act)), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by 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 September 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 September 30, 2007, we had a cumulative loss of \$780.1 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

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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

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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 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, aflibercept, VEGF Trap-Eye, and riloncept, in a wide variety of indications. We are studying aflibercept 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.

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***The data from the Phase 3 clinical program for riloncept in CAPS (Cryopyrin-Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of riloncept.***

We recently submitted a BLA to the FDA for riloncept 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 riloncept. 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 riloncept, 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 riloncept 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 riloncept 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.

Our aflibercept (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

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potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These serious and potentially life-threatening 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 aflibercept 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 riloncept 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.), riloncept affects the immune defense system of the body by blocking some of its functions. Therefore, riloncept 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 riloncept. One subject with adult Still's disease in a study of riloncept 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 riloncept in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of riloncept have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of riloncept.

***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 riloncept for rheumatoid arthritis and other 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 riloncept.

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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 aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept 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. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and riloncept, 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

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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 aflibercept or the 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 aflibercept or the 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 aflibercept or the 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 aflibercept or the 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 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.



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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.***

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.***

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

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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 aflibercept (VEGF Trap) is terminated, our business operations and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be harmed.***

We rely heavily on sanofi-aventis to assist with the development of the aflibercept program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept 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 aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept 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 aflibercept 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 aflibercept program.

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***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

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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 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

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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 aflibercept 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 aflibercept 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

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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 aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept 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 rilonacept. 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 group of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over rilonacept.

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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 group 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 group 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 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,

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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.***

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.



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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 September 30, 2007, our seven largest shareholders beneficially owned 42.3% 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 September 30, 2007. As of September 30, 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 September 30, 2007, holders of Class A Stock held 26.2% 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 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 September 30, 2007:

our current executive officers and directors beneficially owned 12.9% 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 September 30, 2007, and 30.2% 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 September 30, 2007; and

our seven largest shareholders beneficially owned 42.3% 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

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Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2007. In addition, these seven shareholders held 49.6% 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 September 30, 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 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.

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**Item 6. Exhibits**

(a) Exhibits

**Exhibit**

**Number Description**

- 10.1\* - First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
- 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 Exchange Act of 1934.
- 31.2 - Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
- 32 - Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

\* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

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**SIGNATURE**

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

Regeneron Pharmaceuticals, Inc.

Date: November 7, 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)

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