

REGENERON PHARMACEUTICALS INC

Form 10-Q

November 06, 2006

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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, 2006

**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). ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of October 31, 2006:

| Class of Common Stock            | Number of Shares |
|----------------------------------|------------------|
| Class A Stock, \$0.001 par value | 2,296,928        |
| Common Stock, \$0.001 par value  | 55,153,986       |

**REGENERON PHARMACEUTICALS, INC.**  
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**September 30, 2006**

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****REGENERON PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2006 AND DECEMBER 31, 2005 (Unaudited)***(In thousands, except share data)*

|   | <b>September<br/>30,<br/>2006</b> | <b>December<br/>31,<br/>2005</b> |
|---|-----------------------------------|----------------------------------|
| <b>ASSETS</b>   |                                   |                                  |
| Current assets  |                                   |                                  |
| Cash and cash equivalents   | \$ 167,662                        | \$ 184,508                       |
| Marketable securities   | 94,227                            | 114,037                          |
| Accounts receivable   | 7,940                             | 36,521                           |
| Prepaid expenses and other current assets   | 3,920                             | 3,422                            |
| Inventory   |                                   | 2,904                            |
| Total current assets  | 273,749                           | 341,392                          |
| Marketable securities   | 27,708                            | 18,109                           |
| Property, plant, and equipment, at cost, net of accumulated depreciation and amortization   | 51,035                            | 60,535                           |
| Other assets  | 2,694                             | 3,465                            |
| Total assets  | \$ 355,186                        | \$ 423,501                       |
| <b>LIABILITIES and STOCKHOLDERS EQUITY</b>  |                                   |                                  |
| Current liabilities   |                                   |                                  |
| Accounts payable and accrued expenses   | \$ 19,054                         | \$ 23,337                        |
| Deferred revenue, current portion   | 13,644                            | 17,020                           |
| Total current liabilities   | 32,698                            | 40,357                           |
| Deferred revenue  | 60,015                            | 69,142                           |
| Notes payable   | 200,000                           | 200,000                          |
| Total liabilities   | 292,713                           | 309,499                          |
| 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 - 2,296,928 in 2006 and 2,347,073 in 2005 | 2                                 | 2                                |
| Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 54,784,449 in 2006 and 54,092,268 in 2005            | 55                                | 54                               |
| Additional paid-in capital  | 719,157                           | 700,011                          |

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|  |            |            |
|--|------------|------------|
| Unearned compensation                      |            | (315)      |
| Accumulated deficit                        | (656,646)  | (585,280)  |
| Accumulated other comprehensive loss       | (95)       | (470)      |
| Total stockholders' equity                 | 62,473     | 114,002    |
| Total liabilities and stockholders' equity | \$ 355,186 | \$ 423,501 |

**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<br/>September 30,</b> |             | <b>Nine months ended<br/>September 30</b> |             |
|--|---|-------------|---|-------------|
|  | <b>2006</b>                                 | <b>2005</b> | <b>2006</b>                               | <b>2005</b> |
| Revenues   |   |             |   |             |
| Contract research and development  | \$ 11,448                                   | \$ 11,533   | \$ 41,026                                 | \$ 38,580   |
| Contract manufacturing   | 4,176                                       | 4,661       | 12,075                                    | 10,189      |
|  | 15,624                                      | 16,194      | 53,101                                    | 48,769      |
| Expenses   |   |             |   |             |
| Research and development   | 34,808                                      | 41,116      | 101,290                                   | 117,670     |
| Contract manufacturing   | 3,054                                       | 3,246       | 7,716                                     | 7,412       |
| General and administrative   | 6,019                                       | 6,219       | 18,264                                    | 18,581      |
|  | 43,881                                      | 50,581      | 127,270                                   | 143,663     |
| Loss from operations   | (28,257)                                    | (34,387)    | (74,169)                                  | (94,894)    |
| Other income (expense)   |   |             |   |             |
| Other contract income  |   |             |   | 30,640      |
| Investment income  | 3,858                                       | 2,746       | 11,023                                    | 7,515       |
| Interest expense   | (3,011)                                     | (3,011)     | (9,033)                                   | (9,035)     |
|  | 847   | (265)       | 1,990                                     | 29,120      |
| Net loss before cumulative effect of a<br>change in accounting principle                               | (27,410)                                    | (34,652)    | (72,179)                                  | (65,774)    |
| Cumulative effect of adopting Statement of<br>Financial Accounting Standards No. 123R<br>( SFAS 123R ) |   |             | 813                                       |             |
| Net loss   | \$ (27,410)                                 | \$ (34,652) | \$ (71,366)                               | \$ (65,774) |
| Net loss per share amounts, basic and<br>diluted:  |   |             |   |             |
| Net loss before cumulative effect of a<br>change in accounting principle                               | \$ (0.48)                                   | \$ (0.62)   | \$ (1.27)                                 | \$ (1.18)   |
| Cumulative effect of adopting SFAS 123R  |   |             | 0.02                                      |             |

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|  |             |           |           |           |
|--|-------------|-----------|-----------|-----------|
| Net loss   | \$ (0.48)   | \$ (0.62) | \$ (1.25) | \$ (1.18) |
| Weighted average shares outstanding, basic and diluted | 57,011<br>4 | 55,978    | 56,884    | 55,903    |

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**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)**  
**For the nine months ended September 30, 2006**  
*(In thousands)*

|   | Class A |        | Common |        | Additional      |                       | Accumulated         |                                | Other                |                                | Total |
|---|---------|--------|--------|--------|-----------------|-----------------------|---------------------|--------------------------------|----------------------|--------------------------------|-------|
|   | Shares  | Amount | Shares | Amount | Paid-in Capital | Unearned Compensation | Accumulated Deficit | Accumulated Comprehensive Loss | Stockholders' Equity | Accumulated Comprehensive Loss |       |
| <b>Balance, December 31, 2005</b>   | 2,347   | \$ 2   | 54,092 | \$ 54  | \$ 700,011      | \$ (315)              | \$(585,280)         | \$(470)                        | \$ 114,002           |                                |       |
| Issuance of Common Stock in connection with exercise of stock options, net of shares tendered |         |        | 523    | 1      | 4,882           |                       |                     |                                |                      | 4,883                          |       |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution          |         |        | 121    |        | 1,884           |                       |                     |                                |                      | 1,884                          |       |
| Conversion of Class A Stock to Common Stock   | (50)    |        | 50     |        |                 |                       |                     |                                |                      |                                |       |
| Forfeitures of restricted Common Stock under Long-Term Incentive Plan                         |         |        | (2)    |        |                 |                       |                     |                                |                      |                                |       |
| Stock-based compensation expense  |         |        |        |        | 13,508          |                       |                     |                                |                      | 13,508                         |       |
| Adjustment to reduce unearned compensation upon adoption of SFAS 123R                         |         |        |        |        | (315)           | 315                   |                     |                                |                      |                                |       |
| Cumulative effect of adopting SFAS 123R   |         |        |        |        | (813)           |                       |                     |                                |                      | (813)                          |       |
| Net loss  |         |        |        |        |                 |                       | (71,366)            |                                | (71,366)             | \$(71,366)                     |       |



Change in net  
unrealized loss  
on marketable  
securities

375 375 375

**Balance,  
September 30,  
2006**

2,297 \$ 2 54,784 \$ 55 \$ 719,157 \$(656,646) \$ (95) \$ 62,473 \$(70,991)

**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<br/>30,</b> |             |
|--|--|-------------|
|  | <b>2006</b>                                | <b>2005</b> |
| Cash flows from operating activities   |  |             |
| Net loss   | \$ (71,366)                                | \$ (65,774) |
| Adjustments to reconcile net loss to net cash provided by operating activities   |  |             |
| Depreciation and amortization  | 11,196                                     | 11,624      |
| Non-cash compensation expense  | 13,542                                     | 17,624      |
| Cumulative effect of a change in accounting principle                            | (813)                                      |             |
| Changes in assets and liabilities  |  |             |
| Decrease in accounts receivable  | 28,581                                     | 32,566      |
| Decrease (increase) in prepaid expenses and other assets                         | 364  | (956)       |
| Decrease in inventory  | 3,524                                      | 1,208       |
| Decrease in deferred revenue   | (12,503)                                   | (9,398)     |
| (Decrease) increase in accounts payable, accrued expenses, and other liabilities | (2,753)                                    | 2,657       |
| Total adjustments  | 41,138                                     | 55,325      |
| Net cash used in operating activities  | (30,228)                                   | (10,449)    |
| Cash flows from investing activities   |  |             |
| Purchases of marketable securities   | (252,037)                                  | (91,078)    |
| Sales or maturities of marketable securities                                     | 261,749                                    | 185,882     |
| Capital expenditures   | (1,603)                                    | (4,613)     |
| Net cash provided by investing activities  | 8,109                                      | 90,191      |
| Cash flows from financing activities   |  |             |
| Net proceeds from the issuance of stock  | 4,883                                      | 1,122       |
| Other  | 390  |             |
| Net cash provided by financing activities  | 5,273                                      | 1,122       |
| Net (decrease) increase in cash and cash equivalents                             | (16,846)                                   | 80,864      |
| Cash and cash equivalents at beginning of period                                 | 184,508                                    | 95,229      |
| Cash and cash equivalents at end of period                                       | \$ 167,662                                 | \$ 176,093  |



**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, 2005 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, 2005.

**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. For the three and nine months ended September 30, 2006 and 2005, the Company reported net losses and, 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<br>30, |             |
|---|-------------------------------------|-------------|
|   | 2006                                | 2005        |
| Net loss (Numerator)                                | \$ (27,410)                         | \$ (34,652) |
| Weighted-average shares, in thousands (Denominator) | 57,011                              | 55,978      |
| Basic and diluted net loss per share                | \$ (0.48)                           | \$ (0.62)   |

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

|   | Nine Months Ended September<br>30, |             |
|---|------------------------------------|-------------|
|   | 2006                               | 2005        |
| Net loss (Numerator)                                | \$ (71,366)                        | \$ (65,774) |
| Weighted-average shares, in thousands (Denominator) | 56,884                             | 55,903      |
| Basic and diluted net loss per share                | \$ (1.25)                          | \$ (1.18)   |

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, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

|                                       | Three months ended September<br>30, |          |
|---------------------------------------|-------------------------------------|----------|
|                                       | 2006                                | 2005     |
| Stock Options:                        |                                     |          |
| Weighted average number, in thousands | 14,082                              | 13,236   |
| Weighted average exercise price       | \$ 14.35                            | \$ 14.54 |
| Restricted Stock:                     |                                     |          |
| Weighted average number, in thousands |                                     | 149      |
| Convertible Debt:                     |                                     |          |
| Weighted average number, in thousands | 6,611                               | 6,611    |
| Conversion price                      | \$ 30.25                            | \$ 30.25 |

|                                       | Nine months ended September<br>30, |          |
|---------------------------------------|------------------------------------|----------|
|                                       | 2006                               | 2005     |
| Stock Options:                        |                                    |          |
| Weighted average number, in thousands | 14,220                             | 13,335   |
| Weighted average exercise price       | \$ 14.31                           | \$ 14.61 |
| Restricted Stock:                     |                                    |          |
| Weighted average number, in thousands | 31                                 | 188      |
| Convertible Debt:                     |                                    |          |
| Weighted average number, in thousands | 6,611                              | 6,611    |
| Conversion price                      | \$ 30.25                           | \$ 30.25 |

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**REGENERON PHARMACEUTICALS, INC.**

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

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

**3. Stock-based Employee Compensation**

***Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R***

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ( SFAS ) 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$813 and is included in the Company's operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on the Company's loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to the Company's cash flows for these respective periods.

***Long-Term Incentive Plans***

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ( 2000 Incentive Plan ), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals,

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

Inc. 1990 Long-Term Incentive Plan ( 1990 Incentive Plan ) that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. The 1990 Incentive Plan has expired and there will be no future awards from the 1990 Incentive Plan. The Company has issued Incentive Stock Options ( ISOs ) and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of September 30, 2006, there were 6,563,402 shares available for future grants under the 2000 Incentive Plan.

*a. Stock Options*

At September 30, 2006, there were 13,967,474 stock options outstanding with exercise prices ranging from \$4.83 to \$51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents in January 2005 vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the nine months ended September 30, 2006 is presented in the following table:

|   | Number<br>Outstanding | Weighted<br>Average<br>Remaining<br>Contractual<br>Life | Weighted<br>Average<br>Exercise<br>Price | Intrinsic<br>Value (in<br>thousands) |
|---|-----------------------|---|--|--------------------------------------|
| Stock options outstanding at January 1, 2006    | 14,719,492            |   | \$ 14.23                                 |                                      |
| Stock options granted                           | 280,900               |   | \$ 14.90                                 |                                      |
| Stock options exercised                         | (552,785)             |   | \$ 9.72                                  |                                      |
| Stock options forfeited                         | (315,115)             |   | \$ 10.47                                 |                                      |
| Stock options expired                           | (165,018)             |   | \$ 24.17                                 |                                      |
| Stock options outstanding at September 30, 2006 | 13,967,474            | 6.30  | \$ 14.39                                 | \$59,450                             |
| Stock options vested and exercisable            | 7,087,863             | 4.89  | \$ 17.79                                 | \$24,221                             |

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**REGENERON PHARMACEUTICALS, INC.**

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

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

The total intrinsic value of stock options exercised during the first nine months of 2006 and 2005 was \$3,548 and \$220, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ( Stock Option Expense ) recognized in operating expenses totaled \$4,762 and \$5,439, respectively, which included \$94 and \$65, respectively, of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled \$13,243, which included \$34 previously capitalized in inventory, and \$16,166, respectively. In addition, for the nine months ended September 30, 2005, \$147 of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was \$19,132 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon the Company's products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

**Fair Value Assumptions:**

The fair value of each option granted during the three and nine months ended September 30, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended September 30, 2006 and 2005 was \$8.30 and \$5.12 per option, respectively. The weighted-average fair value of the options granted during the nine months ended September 30, 2006 and 2005 was \$9.75 and \$5.79 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.



**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                             | 2005      |
| Expected volatility            | 65%                              | 70%       |
| Expected lives from grant date | 5.5 years                        | 5.0 years |
| Expected dividend yield        | 0%                               | 0%        |
| Risk-free interest rate        | 4.74%                            | 4.00%     |

|                                | Nine months ended September 30, |           |
|--------------------------------|---------------------------------|-----------|
|                                | 2006                            | 2005      |
| Expected volatility            | 67%                             | 75%       |
| Expected lives from grant date | 6.5 years                       | 6.2 years |
| Expected dividend yield        | 0%                              | 0%        |
| Risk-free interest rate        | 4.76%                           | 3.96%     |

*b. Restricted Stock*

A summary of the Company's activity related to Restricted Stock awards for the nine months ended September 30, 2006 is presented in the following table:

|  | Number   | Weighted<br>Average Grant<br>Date Fair<br>Value |
|--|----------|---|
| Restricted stock outstanding as of January 1, 2006 | 95,188   | \$ 11.16  |
| Restricted stock released                          | (93,485) | \$ 11.18  |
| Restricted stock forfeited                         | (1,703)  | \$ 9.74   |

Restricted stock outstanding as of September 30, 2006

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the nine months ended September 30, 2006. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation was combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

For the three months ended September 30 2005, the Company recognized compensation expense related to Restricted Stock awards of \$482. For the nine months ended September 30, 2006 and 2005, the Company recognized compensation expense

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

related to Restricted Stock awards of \$299 and \$1,458, respectively. As of September 30, 2006, there were no unvested shares of restricted stock outstanding and all compensation expense related to these awards had been recognized.

**4. Statement of Cash Flows**

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2006 and December 31, 2005 are \$439 and \$234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2005 and December 31, 2004 are \$252 and \$550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are \$1,884 and \$632, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2006 and December 31, 2005 are \$354 and \$1,228, respectively, of accrued interest income. Included in marketable securities at September 30, 2005 and December 31, 2004 are \$1,110 and \$2,607, respectively, of accrued interest income.

**5. Severance Costs**

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as the Company completes activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and

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2006 workforce reductions will approximate \$2.6 million, including \$0.2 million of non-cash expenses in 2005.

Severance costs associated with the workforce reduction plan that were charged to expense, or credited to adjust original cost estimates, during the three and nine months ended September 30, 2006 consist of the following:

|   | Accrued<br>liability<br>at<br>June 30,<br>2006 | Three months ended<br>September 30, 2006<br>Costs<br>charged<br>(credited)<br>to<br>expense | Costs<br>paid<br>or settled<br>in 2006 | Accrued<br>liability at<br>September<br>30,<br>2006 |
|---|--|---|--|---|
| Employee severance, payroll taxes, and benefits | \$ 463   | \$ (44)   | \$ (273)                               | \$ 146  |
| Other severance costs                           | 1  | 6   | (7)                                    |   |
| Total   | \$ 464   | \$ (38)   | \$ (280)                               | \$ 146  |

|   | Accrued<br>liability<br>at<br>December<br>31, 2005 | Nine months ended<br>September 30, 2006<br>Costs<br>charged<br>to<br>expense | Costs<br>paid<br>or settled<br>in 2006 | Accrued<br>liability at<br>September<br>30,<br>2006 |
|---|--|--|--|---|
| Employee severance, payroll taxes, and benefits | \$ 907   | \$ 312   | \$ (1,073)                             | \$ 146  |
| Other severance costs                           | 176  | 26   | (202)                                  |   |
| Total   | \$ 1,083   | \$ 338   | \$ (1,275)                             | \$ 146  |

These severance costs are included in the Company's Statement of Operations for the three and nine months ended September 30, 2006 as follows:

|   | Research &<br>development |
|---|---------------------------|
| Three months ended September 30, 2006           |                           |
| Employee severance, payroll taxes, and benefits | \$ (44)                   |
| Other severance costs                           | 6                         |
| Total   | \$ (38)                   |

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|   | Research &<br>development | General &<br>administrative |
|---|---------------------------|-----------------------------|
| Nine months ended September 30, 2006            |                           |                             |
| Employee severance, payroll taxes, and benefits | \$ 314                    | \$ (2)                      |
| Other severance costs                           | 26                        |                             |
| Total   | \$ 340                    | \$ (2)                      |

For segment reporting purposes (see Note 11), all severance-related expenses are included in the Research & Development segment.

**6. Accounts Receivable**

Accounts receivable as of September 30, 2006 and December 31, 2005 consist of the following:

|  | September<br>30,<br>2006 | December<br>31,<br>2005 |
|--|--------------------------|-------------------------|
| Receivable from the sanofi-aventis Group | \$ 7,326                 | \$ 36,412               |
| Receivable from Merck & Co., Inc.        | 511                      | 27                      |
| Other                                    | 103                      | 82                      |
|  | \$ 7,940                 | \$ 36,521               |

**7. Inventories**

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The Company held no inventories at September 30, 2006. Inventories as of December 31, 2005 consist of the following:

|                   | December<br>31,<br>2005 |
|-------------------|-------------------------|
| Raw materials     | \$ 278                  |
| Work-in-process   | 1,423                   |
| Finished products | 1,203                   |
|                   | \$ 2,904                |

**Table of Contents****REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements (Unaudited)***(Unless otherwise noted, dollars in thousands, except per share data)***8. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses as of September 30, 2006 and December 31, 2005 consist of the following:

|                                       | September<br>30,<br>2006 | December<br>31,<br>2005 |
|---------------------------------------|--------------------------|-------------------------|
| Accounts payable                      | \$ 3,657                 | \$ 4,203                |
| Accrued payroll and related costs     | 5,952                    | 10,713                  |
| Accrued clinical trial expense        | 2,145                    | 3,081                   |
| Accrued expenses, other               | 2,258                    | 3,048                   |
| Interest payable on convertible notes | 5,042                    | 2,292                   |
|                                       | \$ 19,054                | \$ 23,337               |

**9. 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, 2006 and 2005, the components of comprehensive loss are:

|   | Three months ended September<br>30,<br>2006 | 2005        |
|---|---|-------------|
| Net loss  | \$ (27,410)                                 | \$ (34,652) |
| Change in net unrealized gain (loss) on marketable securities | 378   | 27          |
| Total comprehensive loss                                      | \$ (27,032)                                 | \$ (34,625) |

|   | Nine months ended September<br>30,<br>2006 | 2005        |
|---|--|-------------|
| Net loss  | \$ (71,366)                                | \$ (65,774) |
| Change in net unrealized gain (loss) on marketable securities | 375  | 87          |
| Total comprehensive loss                                      | \$ (70,991)                                | \$ (65,687) |

**10. National Institutes of Health Grant**

In September 2006, the Company was awarded a grant from the National Institutes of Health ( NIH ) as part of the NIH's Knockout Mouse Project. The NIH grant provides a minimum of \$17.9 million in funding over a five-year period, subject to compliance with

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its terms and annual funding approvals, for the Company's use of its VelociGen® technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells ( ES Cells ) which can be used to produce knockout mice. The Company will also receive another \$1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In September 2006, we recognized contract research and development revenue of \$57 from the NIH Grant.

**11. Segment Information**

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

*Research and development:* Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

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

The table below presents information about reported segments for the three and nine months ended September 30, 2006 and 2005.

|                               | Three months ended September 30, 2006 |                           |                      |           |
|-------------------------------|---------------------------------------|---------------------------|----------------------|-----------|
|                               | Research &<br>Development             | Contract<br>Manufacturing | Reconciling<br>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       |
|                               | 17                                    |                           |                      |           |

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## Three months ended September 30, 2005

|                               | Research &<br>Development | Contract<br>Manufacturing | Reconciling<br>Items | Total     |
|-------------------------------|---------------------------|---------------------------|----------------------|-----------|
| Revenues                      | \$ 11,533                 | \$ 4,661                  |                      | \$ 16,194 |
| Depreciation and amortization | 3,674                     | (1)                       | \$ 261               | 3,935     |
| Non-cash compensation expense | 5,703                     | 218                       |                      | 5,921     |
| Interest expense              |                           |                           | 3,011                | 3,011     |
| Net (loss) income             | (35,802)                  | 1,415                     | (265) <sup>(2)</sup> | (34,652)  |
| Capital expenditures          | 575                       |                           |                      | 575       |

## Nine months ended September 30, 2006

|                               | Research &<br>Development | Contract<br>Manufacturing | Reconciling<br>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   |

## Nine months ended September 30, 2005

|                               | Research &<br>Development | Contract<br>Manufacturing | Reconciling<br>Items   | Total     |
|-------------------------------|---------------------------|---------------------------|------------------------|-----------|
| Revenues                      | \$ 38,580                 | \$ 10,189                 |                        | \$ 48,769 |
| Depreciation and amortization | 10,841                    | (1)                       | \$ 783                 | 11,624    |
| Non-cash compensation expense | 17,316                    | 308                       |                        | 17,624    |
| Other contract income         | 30,640                    |                           |                        | 30,640    |
| Interest expense              |                           |                           | 9,035                  | 9,035     |
| Net (loss) income             | (67,031)                  | 2,777                     | (1,520) <sup>(2)</sup> | (65,774)  |
| Capital expenditures          | 4,327                     |                           |                        | 4,327     |
| Total assets                  | 72,037                    | 5,380                     | 341,858 <sup>(4)</sup> | 419,275   |

- (1) Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when

the product was  
shipped.



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- (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 SFAS 123R (see Note 3).
- (3) Represents the cumulative effect of adopting SFAS 123R (see Note 3).
- (4) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

**12. 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.

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

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also

provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Management is currently evaluating the potential impact of adopting FIN 48 on the Company's financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. The Company will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 157 on the Company's financial statements.

#### **14. Subsequent Event New Research and Development Agreement**

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC (Bayer) to globally develop, and commercialize outside the United States, the Company's Vascular Endothelial Growth Factor (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 addition, the Company is eligible to receive up to \$110.0 million in

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development and regulatory milestones, including a total of \$40.0 million upon the initiation of Phase 3 trials in defined major indications. The Company is also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

The Company will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, the Company is responsible for any future commercialization of the VEGF Trap-Eye and has retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

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

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

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to the VEGF Trap-Eye.

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**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: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and the IL-1 Trap (rilonacept) in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. In October 2006, we entered into a collaboration with Bayer HealthCare LLC for the development of the VEGF Trap-Eye. 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. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. 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 (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the strength of 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 two new antibody candidates into clinical trials each year going forward beginning in 2007. 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 clinical status of our clinical candidates as of September 30, 2006:

#### **1. VEGF Trap Oncology**

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis. Currently, the collaboration is conducting three Phase 2 studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of SMA. In addition, four new Phase 2 single-agent studies are beginning in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas. We and sanofi-aventis are working to finalize plans with NCI/CTEP for at least six additional trials in different cancer types.

Sanofi-aventis and Regeneron intend to conduct three Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, the first of which is planned to begin in early 2007. Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are in progress in a variety of cancer types to support the planned Phase 3 clinical program. The companies have previously summarized information from two of these safety and tolerability trials. One study is evaluating the VEGF Trap in combination with oxaliplatin, 5-fluorouracil, and leucovorin (FOLFOX4) in a Phase 1 trial of patients with advanced solid tumors. Another study is evaluating the VEGF Trap in combination with irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a Phase 1 trial of patients with advanced solid tumors. Abstracts published in the 2006 ASCO Annual Meeting Proceedings reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

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

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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 is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

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

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See The sanofi-aventis Group Agreement below.)

**2. VEGF Trap Eye Diseases**

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

In 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 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

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eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare and can earn up to \$110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap outside the United States achieve certain specified levels starting at \$200 million. 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. Detailed information about this agreement is included in the section below entitled Collaboration with Bayer HealthCare.

In the second quarter of 2006, we initiated a 150 patient, 12 week, Phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. Regeneron is initiating a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in AMD. A Phase 3 trial of the VEGF Trap-Eye in wet AMD utilizing the new formulation is planned to begin in early 2007.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with DME.

At the 2006 American Society of Retinal Specialists (ASRS) annual meeting in France, we updated the positive preliminary results from a Phase 1 trial of the VEGF Trap-Eye in patients with wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye). Patients were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. In wet AMD, the leakiness of the abnormal blood vessels in the eye can lead to increased retinal thickness. On average, patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness. Excess retinal thickness, as determined by ocular coherence tomography (OCT), is a clinical measure of disease activity in wet AMD. As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness resulting from the disease process was 194 microns at baseline. Following a single intravitreal dose of the VEGF Trap-Eye, median excess retinal thickness was reduced to 60 microns, an improvement that was sustained over a six week period. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline, which was reduced to 27 microns at six weeks after the single dose of the VEGF Trap-Eye.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as  $\leq 15$  letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at six weeks. In the two highest dose groups (2 mg and 4 mg), the mean

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improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

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. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. 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.

### **3. IL-1 Trap (rilonacept) Inflammatory Diseases**

The IL-1 Trap (rilonacept) 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 the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called *CIAS1*-related Autoinflammatory Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In October 2006, we announced positive data from a Phase 3 clinical program designed to provide two separate demonstrations of efficacy for the IL-1 Trap within a single group of adult patients suffering from CAPS. The Phase 3 program of the IL-1 Trap included two studies (Part A and Part B). Both studies met their primary endpoints (Part A:  $p < 0.0001$  and Part B:  $p < 0.001$ ). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

We plan to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2007, following completion of a 24-week open-label extension phase. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive the IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ( $p < 0.0001$ ). Following a 9-week interval during which all patients received the IL-1 Trap, a randomized withdrawal study (Part B) was performed, in which the same patients were re-randomized to either switch to placebo or continue treatment with the IL-1 Trap in a double-



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blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on the IL-1 Trap who had no significant change ( $p < 0.001$ ). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on the IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. The 24-week open-label extension phase is ongoing.

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

We are also evaluating the potential use of the IL-1 Trap in other indications. In particular, based on preclinical evidence that IL-1 appears to play a critical role in gout, we are preparing to initiate an exploratory study in gout in early 2007. In an ongoing pilot study in systemic juvenile idiopathic arthritis (SJIA), we observed evidence of biological activity and clinical response, but also noted clinical variability across the SJIA patients. While we continue to evaluate the IL-1 Trap in these patients, no new studies are currently planned.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap 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 IL-1 Trap currently in clinical development.

### **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

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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, 2006, we had a cumulative loss of \$656.6 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. 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, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2006 and plans over the next 12 months are as follows:

| <b>Product Candidate</b> | <b>2006 Events to Date</b>   | <b>2006-7 Plans</b>  |
|--------------------------|--|--|
| VEGF Trap<br>Oncology    | <p>Initiated Phase 2 studies of the VEGF Trap as a single agent in AOC and NSCLA patients, and in AOC patients with SMA.</p> <p>Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens</p> <p>Reported encouraging preliminary results of the safety and tolerability of intravenous VEGF Trap plus FOLFOX4 and of intravenous VEGF Trap plus LV5FU2-CPT11 in separate Phase 1 trials of patients with advanced solid tumors</p> <p>NCI/CTEP finalized protocols for Phase 2 trials of the VEGF Trap in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas</p> | <p>Initiate up to three efficacy/safety studies of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications</p> <p>Sponsor with the NCI/CTEP at least six additional exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types</p> |

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**Product Candidate**

VEGF Trap-Eye

**2006 Events to Date**

Reported positive preliminary results from Phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg

Initiated Phase 2 trial in wet AMD utilizing intravitreal injections

Initiated safety and tolerability study of the new formulation of the VEGF Trap-Eye in patients with AMD

Initiated Phase 1 trial in DME

Initiated collaboration with Bayer HealthCare

**2006-7 Plans**

Report preliminary results of Phase 2 trial in wet AMD utilizing intravitreal injections

Initiate Phase 3 trial in wet AMD utilizing intravitreal injections of the VEGF Trap-Eye

Explore additional eye disease indications

IL-1 Trap (rilonacept)

Reported positive results from efficacy portion of Phase 3 trial of the IL-1 Trap in CAPS

Reported positive preliminary results from ongoing Phase 1 trial in SJIA

File Biologics License Application with the FDA for CAPS

Evaluate the IL-1 Trap in other disease indications in which IL-1 may play an important role

**Collaboration with Bayer Healthcare**

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the VEGF Trap-Eye. Under the terms of the agreement, Bayer made a non-refundable up-front payment to us of \$75.0 million. In addition, we are eligible to receive up to \$110.0 million in development and regulatory milestones, including a total of \$40.0 million upon the initiation of Phase 3 trials in defined major indications such as wet AMD and DME. We are also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

We will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, we are responsible for any future commercialization of the VEGF Trap-Eye and have retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

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

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

2009 and thereafter: All expenses shared equally.

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If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

### **National Institutes of Health Grant**

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We will use our VelociGene® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We have also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our VelociGene technology in the Knockout Mouse Project. We will generate a collection of targeting vectors and targeted mouse embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we will be entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We will have the right to use, for any purpose, all materials generated by us and the research consortium.

### **Accounting for Stock-based Employee Compensation**

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. (SFAS) 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation- Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions

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in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to our cash flows for these respective periods.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ( Stock Option Expense ) recognized in operating expenses totaled \$4.8 million and \$5.4 million, respectively, which, in both periods, included \$0.1 million in each period of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled \$13.2 million and \$16.2 million, respectively. In addition, for the nine months ended September 30, 2005, \$0.1 million of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was \$19.1 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options performance condition becomes probable of attainment.

*Assumptions*

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

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values of the assumptions we used in computing the fair value of option grants during the three and nine months ended September 30, 2006 and 2005:

|                                | <b>Three months ended September 30,</b> |             |
|--------------------------------|---|-------------|
|                                | <b>2006</b>                             | <b>2005</b> |
| Expected volatility            | 65%                                     | 70%         |
| Expected lives from grant date | 5.5 years                               | 5.0 years   |
| Expected dividend yield        | 0%                                      | 0%          |
| Risk-free interest rate        | 4.74%                                   | 4.00%       |

|                                | <b>Nine months ended September 30,</b> |             |
|--------------------------------|--|-------------|
|                                | <b>2006</b>                            | <b>2005</b> |
| Expected volatility            | 67%                                    | 75%         |
| Expected lives from grant date | 6.5 years                              | 6.2 years   |
| Expected dividend yield        | 0%                                     | 0%          |
| Risk-free interest rate        | 4.76%                                  | 3.96%       |

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

**Results of Operations*****Three Months Ended September 30, 2006 and 2005******Net Loss:***

We reported a net loss of \$27.4 million, or \$0.48 per share (basic and diluted), for the third quarter of 2006 compared to a net loss of \$34.7 million, or \$0.62 per share (basic and diluted), for the third quarter of 2005.

***Revenues:***

Revenues for the three months ended September 30, 2006 and 2005 consist of the following:

| <b>(In millions)</b>                          | <b>2006</b> | <b>2005</b> | <b>Increase<br/>(Decrease)</b> |
|---|-------------|-------------|--------------------------------|
| Contract research & development revenue       |             |             |                                |
| The sanofi-aventis Group                      | \$ 10.0     | \$ 11.2     | \$ (1.2)                       |
| Other   | 1.4         | 0.3         | 1.1                            |
| Total contract research & development revenue | 11.4        | 11.5        | (0.1)                          |
| Contract manufacturing revenue                | 4.2         | 4.7         | (0.5)                          |
| Total revenue                                 | \$ 15.6     | \$ 16.2     | \$ (0.6)                       |

We earn contract research and development revenue from sanofi-aventis in connection with the companies VEGF Trap collaboration 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

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2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

**Sanofi-aventis Contract Research & Development Revenue**

| <i>(In millions)</i>   | <b>Three months ended September<br/>30,</b> |             |
|--|---|-------------|
|  | <b>2006</b>                                 | <b>2005</b> |
| Regeneron expense reimbursement                              | \$ 7.0                                      | \$ 8.9      |
| Recognition of deferred revenue related to up-front payments | 3.0   | 2.3         |
| Total  | \$ 10.0                                     | \$ 11.2     |

Sanofi-aventis reimbursement of our VEGF Trap expenses decreased in the third quarter of 2006 from the same period in 2005, primarily due to lower costs in the third quarter of 2006 related to our manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis up-front payments increased in the third quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies VEGF Trap collaboration to include Japan. As of September 30, 2006, \$72.2 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract manufacturing revenue relates 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. Contract manufacturing revenue decreased in the third quarter of 2006 from the same period of 2005 as we shipped less product to Merck in 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 and 2005 were \$0.4 million and \$0.5 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. Merck deferred revenue has been recognized as product is shipped, based upon Merck's order quantities during the term of the agreement. In September 2006, we made the final shipment of product to Merck under the Merck agreement and the remaining deferred revenue associated with the capital improvement reimbursements was recognized. Subsequent to the October 2006 expiration of the Merck agreement, we do not expect to receive any further contract manufacturing revenue from Merck.

***Expenses:***

Total operating expenses decreased to \$43.9 million in the third quarter of 2006 from \$50.6 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 574 in the third quarter of 2006 from 728 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005. (See *Severance Costs* below.)

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Operating expenses in the third quarter of 2006 and 2005 include a total of \$4.7 million and \$5.5 million of Stock Option Expense, respectively, as detailed below:

| <i>(In millions)</i>       | <b>For the three months ended September 30,<br/>2006</b>                     |                                     |                                     |
|----------------------------|--|-------------------------------------|-------------------------------------|
|                            | <b>Expenses<br/>before<br/>inclusion<br/>of Stock<br/>Option<br/>Expense</b> | <b>Stock<br/>Option<br/>Expense</b> | <b>Expenses<br/>as<br/>Reported</b> |
| <b>Expenses</b>            |  |                                     |                                     |
| 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                             |

| <i>(In millions)</i>       | <b>For the three months ended September 30,<br/>2005</b>                     |                                     |                                     |
|----------------------------|--|-------------------------------------|-------------------------------------|
|                            | <b>Expenses<br/>before<br/>inclusion<br/>of Stock<br/>Option<br/>Expense</b> | <b>Stock<br/>Option<br/>Expense</b> | <b>Expenses<br/>as<br/>Reported</b> |
| <b>Expenses</b>            |  |                                     |                                     |
| Research and development   | \$ 37.8  | \$ 3.3                              | \$ 41.1                             |
| Contract manufacturing     | 3.0  | 0.3                                 | 3.3                                 |
| General and administrative | 4.3  | 1.9                                 | 6.2                                 |
| Total operating expenses   | \$ 45.1  | \$ 5.5                              | \$ 50.6                             |

*Research and Development Expenses:*

Research and development expenses decreased to \$34.8 million in the third quarter of 2006 from \$41.1 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2006 and 2005:

| <i>(In millions)</i>                       | <b>Three months ended September 30,</b> |                           |                                |
|--|---|---------------------------|--------------------------------|
|  | <b>2006</b>                             | <b>2005<sup>(1)</sup></b> | <b>Increase<br/>(Decrease)</b> |
| <b>Research and development expenses</b>   |   |                           |                                |
| Payroll and benefits (2)                   | \$ 11.0                                 | \$ 12.8                   | (\$1.8)                        |
| Clinical trial expenses                    | 3.1                                     | 7.5                       | (4.4)                          |
| Clinical manufacturing costs (3)           | 10.0                                    | 10.8                      | (0.8)                          |
| Research and preclinical development costs | 5.5                                     | 4.5                       | 1.0                            |
| Occupancy and other operating costs        | 5.2                                     | 5.5                       | (0.3)                          |
| Total research and development             | \$ 34.8                                 | \$ 41.1                   | (\$6.3)                        |



- (1) For the major categories of research and development expenses, amounts for the three months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the three months ended September 30, 2005 are unchanged from amounts previously reported.
- (2) Includes \$2.3 million and \$2.8 million of Stock Option Expense for the three months ended September 30, 2006 and 2005, respectively.
- (3) 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  
\$0.5 million of  
Stock Option  
Expense for  
both the three  
months ended  
September 30,  
2006 and 2005.

Payroll and benefits decreased principally due to our lower headcount in the third quarter of 2006, as described above. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006, as we discontinued clinical development of the IL-1 Trap in adult rheumatoid

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arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased as we were not actively manufacturing clinical supplies of our drug candidates during the third quarter of 2006. Research and preclinical development costs increased primarily due to higher third-party pre-clinical testing costs in connection with our VEGF Trap and VEGF Trap-Eye programs. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

*Contract Manufacturing Expenses:*

Contract manufacturing expenses decreased to \$3.1 million in the third quarter of 2006 from \$3.3 million in the comparable quarter of 2005 primarily because we shipped less product to Merck.

*General and Administrative Expenses:*

General and administrative expenses decreased to \$6.0 million in the third quarter of 2006 from \$6.2 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and legal expenses related to general corporate matters.

*Other Income and Expense:*

Investment income increased to \$3.9 million in the third quarter of 2006 from \$2.7 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$3.0 million in the third quarter of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

***Nine Months Ended September 30, 2006 and 2005***

*Net Loss:*

We reported a net loss of \$71.4 million, or \$1.25 per share (basic and diluted), for the first nine months of 2006 compared to a net loss of \$65.8 million, or \$1.18 per share (basic and diluted), for the same period of 2005. Results for the first nine months of 2005 included a \$25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap-Eye.

**Table of Contents***Revenues:*

Revenues for the nine months ended September 30, 2006 and 2005 consist of the following:

| <i>(In millions)</i>                          | <b>2006</b> | <b>2005</b> | <b>Increase<br/>(Decrease)</b> |
|---|-------------|-------------|--------------------------------|
| Contract research & development revenue       |             |             |                                |
| The sanofi-aventis Group                      | \$ 38.7     | \$ 30.4     | \$ 8.3                         |
| The Procter & Gamble Company                  |             | 6.0         | (6.0)                          |
| Other   | 2.3         | 2.2         | 0.1                            |
| Total contract research & development revenue | 41.0        | 38.6        | 2.4                            |
| Contract manufacturing revenue                | 12.1        | 10.2        | 1.9                            |
| Total revenue                                 | \$ 53.1     | \$ 48.8     | \$ 4.3                         |

We earn contract research and development revenue from sanofi-aventis in connection with the companies VEGF Trap collaboration 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 payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104.

**Sanofi-aventis Contract Research & Development Revenue**

| <i>(In millions)</i>   | <b>Nine months ended September<br/>30,</b> |             |
|--|--|-------------|
|  | <b>2006</b>                                | <b>2005</b> |
| Regeneron expense reimbursement                              | \$ 29.6                                    | \$ 23.4     |
| Recognition of deferred revenue related to up-front payments | 9.1  | 7.0         |
| Total  | \$ 38.7                                    | \$ 30.4     |

Sanofi-aventis reimbursement of our VEGF Trap expenses increased in the first nine months of 2006 from the same period in 2005, primarily due to higher costs related to our manufacture of VEGF Trap clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis up-front payments also increased in the first nine months of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies VEGF Trap collaboration to include Japan.

Contract research and development revenue earned from Procter & Gamble decreased in the first nine months of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

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Contract manufacturing revenue increased in the first nine months of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Included in contract manufacturing revenue in the first nine months of 2006 and 2005 were \$1.2 million and \$1.1 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production.

*Expenses:*

Total operating expenses decreased to \$127.3 million in the first nine months of 2006 from \$143.7 million in the same period of 2005, due, in part, to our lower headcount, as previously described above. (Also see Severance Costs below.)

Operating expenses in the first nine months of 2006 and 2005 include a total of \$13.2 million and \$16.2 million of Stock Option Expense, respectively, as detailed below:

| <i>(In millions)</i>       | <b>For the nine months ended September 30, 2006</b>                          |                                     |                                     |
|----------------------------|--|-------------------------------------|-------------------------------------|
|                            | <b>Expenses<br/>before<br/>inclusion<br/>of Stock<br/>Option<br/>Expense</b> | <b>Stock<br/>Option<br/>Expense</b> | <b>Expenses<br/>as<br/>Reported</b> |
| <b>Expenses</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                            |

| <i>(In millions)</i>       | <b>For the nine months ended September 30, 2005</b>                          |                                     |                                     |
|----------------------------|--|-------------------------------------|-------------------------------------|
|                            | <b>Expenses<br/>before<br/>inclusion<br/>of Stock<br/>Option<br/>Expense</b> | <b>Stock<br/>Option<br/>Expense</b> | <b>Expenses<br/>as<br/>Reported</b> |
| <b>Expenses</b>            |  |                                     |                                     |
| Research and development   | \$ 107.6   | \$ 10.1                             | \$ 117.7                            |
| Contract manufacturing     | 7.1  | 0.3                                 | 7.4                                 |
| General and administrative | 12.8   | 5.8                                 | 18.6                                |
| Total operating expenses   | \$ 127.5   | \$ 16.2                             | \$ 143.7                            |

*Research and Development Expenses:*

Research and development expenses decreased to \$101.3 million in the first nine months of 2006 from \$117.7 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2006 and 2005:

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|  | Nine months ended September 30, |                     |                        |
|--|---------------------------------|---------------------|------------------------|
|  | 2006                            | 2005 <sup>(1)</sup> | Increase<br>(Decrease) |
| <b>Research and development expenses</b>   |                                 |                     |                        |
| Payroll and benefits (2)                   | \$ 32.7                         | \$ 38.4             | \$ (5.7)               |
| Clinical trial expenses                    | 11.0                            | 16.1                | (5.1)                  |
| Clinical manufacturing costs (3)           | 28.3                            | 32.1                | (3.8)                  |
| Research and preclinical development costs | 13.3                            | 14.5                | (1.2)                  |
| Occupancy and other operating costs        | 16.0                            | 16.6                | (0.6)                  |
| <br>Total research and development         | <br>\$ 101.3                    | <br>\$ 117.7        | <br>\$ (16.4)          |

(1) For the major categories of research and development expenses, amounts for the nine months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the nine months ended September 30, 2005 are unchanged from amounts previously reported.

(2) Includes \$6.1 million and \$8.4 million of Stock Option Expense for the nine months

ended  
September 30,  
2006 and 2005,  
respectively.

- (3) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.2 million and \$1.6 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first nine months of 2006. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006 as we discontinued clinical development of the IL-1 Trap in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing IL-1 Trap clinical supplies, which were partially offset by higher costs related to manufacturing VEGF Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

*Contract Manufacturing Expenses:*

Contract manufacturing expenses increased to \$7.7 million in the first nine months of 2006 from \$7.4 million in the comparable period of 2005 primarily because we shipped more product to Merck.

*General and Administrative Expenses:*

General and administrative expenses decreased to \$18.3 million in the first nine months of 2006 from \$18.6 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and administrative personnel-related costs.

*Other Income and Expense:*

As described above, in January 2005 we received a one-time \$25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first nine months of 2005.



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In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time \$5.6 million payment to us, which we recognized as other contract income in the first nine months of 2005.

Investment income increased to \$11.0 million in the first nine months of 2006 from \$7.5 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$9.0 million in the first nine months of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

### **Liquidity and Capital Resources**

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis and Merck, and investment income.

#### ***Nine Months Ended September 30, 2006 and 2005***

##### ***Cash Used in Operations:***

At September 30, 2006, we had \$289.6 million in cash, cash equivalents, and marketable securities compared with \$316.7 million at December 31, 2005. In January 2006, we received a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first nine months of 2006, our net loss was \$71.4 million; however, cash used in our operations was only \$30.2 million, principally because (i) the above-described \$25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006, and (ii) we recognized non-cash compensation expense of \$13.5 million and depreciation and amortization of \$11.2 million for the first nine months of 2006. In the first nine months of 2005, our net loss was \$65.8 million; however, cash used in our operations was only \$10.4 million, principally due to (i) receipts during this period from the sanofi-aventis Group for reimbursement of VEGF Trap development expenses incurred by us and a \$25.0 million clinical milestone payment earned in December 2004 and (ii) recognition of non-cash compensation expense of \$17.6 million and depreciation and amortization of \$11.6 million for the first nine months of 2005.

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

Net cash provided by investing activities was \$8.1 million in the first nine months of 2006 compared to \$90.2 million in the same period of 2005, due primarily to a decrease in sales or maturities of marketable securities net of purchases. In the first nine months of 2006, sales or maturities of marketable securities exceeded purchases by \$9.7 million, whereas in the same period of 2005, sales or maturities of marketable securities exceeded purchases by \$94.8 million.

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*Cash Provided by Financing Activities:*

Cash provided by financing activities increased to \$5.3 million in the first nine months of 2006 from \$1.1 million in the same period in 2005 due primarily to an increase in payments in connection with exercises of stock options.

***The sanofi-aventis Group Agreement:***

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

***The Bayer Healthcare Agreement:***

Under our collaboration agreement with Bayer, Bayer made a non-refundable, up-front payment of \$75.0 million to us in October 2006. Agreed upon development expenses incurred by both companies during the term of the collaboration will be shared as follows:

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

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

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

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### ***Severance Costs:***

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as we complete activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and 2006 workforce reductions will approximate \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.4 million was charged to expense in the first nine months of 2006.

### ***Capital Expenditures:***

Our additions to property, plant, and equipment totaled \$1.8 million and \$4.3 million for the first nine months of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately \$2 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

### ***Funding Requirements:***

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer. We have entered into discussions regarding a new long-term operating lease for our laboratory and office facilities in Tarrytown, New York, as the operating lease for our current Tarrytown facilities expires in December of 2007 and 2009. We expect to continue to

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incur significant lease costs in future years. 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.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2009, 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. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of September 30, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to \$200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

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

During the nine months ended September 30, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

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

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Our management is currently evaluating the potential impact of adopting FIN 48 on our financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ( GAAP ), and expands disclosures about fair value measurements. We will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 157 on our financial statements.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately \$0.5 million and \$0.8 million change in the fair market value of our investment portfolio at September 30, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at September 30, 2006, compared to September 30, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of September 2006 versus the end of September 2005.

### **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.

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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, 2006 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, 2005 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, 2006, we had a cumulative loss of \$656.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Until October 31, 2006, we received contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck expired in October 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

***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.***

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We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

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

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

### **Risks Related to Development of Our Product Candidates**

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than 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.

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We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap 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, 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 the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

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

***The data from the phase 3 clinical program for the IL-1 Trap in CAPS (CIAS1-related Autoinflammatory Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of the IL-1 Trap.***

The efficacy and safety data from the phase 3 clinical program for the IL-1 Trap in CAPS may be inadequate to support approval for its commercialization in this indication. Moreover, if the safety data from the ongoing clinical trials testing the IL-1 Trap are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for the IL-1 Trap or we may be forced to delay the filing. 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 the IL-1 Trap, 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 the IL-1 Trap 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 the IL-1 Trap 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,

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injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

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

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

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an auto-immune type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created

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at a later date in some cases even after pivotal clinical trials have been completed. Subjects who received IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, which could adversely impact the development of such candidates.

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

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

### **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.

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

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

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

### **Regulatory and Litigation Risks**

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

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval 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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***If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.***

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

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

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

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

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

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

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an

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unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

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

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

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

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

We will 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. 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

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

### **Risks Related to the Manufacture of Our Product Candidates**

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

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

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

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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 API for our own clinical and preclinical candidates. Under a long-term manufacturing agreement with Merck, which expired in October 2006, we also produced an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. Since we no longer use our facilities to manufacture the Merck intermediate, and if 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 with European regulatory requirements, our clinical development activities may be delayed or interrupted.



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### **Risks Related to Commercialization of Products**

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

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye, and we may be unsuccessful in developing our own sales, marketing, and distribution organization. ***Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.***

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings.

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This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, 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. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor (Macugen®) for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of wet AMD and other eye indications that was approved by the FDA in June 2006. 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, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The National Eye Institute has recently received funding for a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. The marketing approval of Macugen and Lucentis and the potential off-label use of Avastin 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 or Macugen, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin 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® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists 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 the IL-1 Trap, 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, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

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We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS1* gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

***The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party 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 intend to file an application with the FDA seeking approval to market the IL-1 Trap for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize the IL-1 Trap. Physicians may not prescribe the IL-1 Trap and CAPS patients may not be able to afford the IL-1 Trap if third party payers do not agree to reimburse the cost of IL-1 Trap therapy and this would adversely affect our ability to commercialize the IL-1 Trap 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 the IL-1 Trap, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

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

### **Risk Related to Employees**

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

We are highly dependent on 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, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer,

Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Therapeutics and Clinical Program Development, Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations, and Peter Powchik, M.D., our Senior Vice President, Clinical Development. 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.

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**Risks Related to Our Common Stock**

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

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

progress, delays, or adverse results in clinical trials;

announcement of technological innovations or product candidates by us or competitors;

fluctuations in our operating results;

public concern as to the safety or effectiveness of our product candidates;

developments in our relationship with collaborative partners;

developments in the biotechnology industry or in government regulation of healthcare;

large sales of our common stock by our executive officers, directors, or significant shareholders;

arrivals and departures of key personnel; and

general market conditions.

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

***Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.***

A small number of our shareholders beneficially own a substantial amount of our common stock. As of September 30, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 46.6% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. As of September 30, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% 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.***

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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, 2006, holders of Class A Stock held 29.5% 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, 2006:

our current officers and directors beneficially owned 14.4% 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, 2006, and 33.1% 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, 2006; and

our seven largest shareholders beneficially owned 46.6% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. In addition, these seven shareholders held 53.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of September 30, 2006.

***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

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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 many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a change in control of the Company, as defined in the plan.

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**Item 6. Exhibits**

(a) Exhibits

**Exhibit**

**Number**

**Description**

|      |  |
|------|--|
| 10.1 | License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc. |
| 12.1 | Statement re: computation of ratio of earnings to combined fixed charges.  |
| 31.1 | Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.   |
| 31.2 | Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.   |
| 32   | Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.   |



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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 6, 2006

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

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