PROGENICS PHARMACEUTICALS INC

Form 10-Q May 09, 2008

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2008

OR

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

For the transition period from ______ to _____

Commission file number 000-23143

PROGENICS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation or organization)

13-3379479 (I.R.S. Employer Identification No.)

777 Old Saw Mill River Road Tarrytown, New York 10591 (Address of principal executive offices) (Zip Code)

(914) 789-2800 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

| Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer o |
|---|
| a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting |
| company" in Rule 12b-2 of the Exchange Act: |

| company in Rule 12b-2 of the Exchange Act: | |
|---|--------------------------------|
| Large accelerated filer " | Accelerated filer x |
| Non-accelerated filer " | Smaller reporting |
| company " | |
| (Do not check if a smaller reporting company) | |
| Indicate by check mark whether the registrant is a shell company (as defined in Rule Yes o No x | e 12b-2 of the Exchange Act). |
| As of May 7, 2008 there were 30,021,933 shares of common stock, par value \$.0013 putstanding. | 3 per share, of the registrant |
| | |
| | |
| | |

PROGENICS PHARMACEUTICALS, INC.

INDEX

| | | Page |
|----------|---|------|
| | | No. |
| Part I | FINANCIAL INFORMATION | |
| Item 1. | Financial Statements (unaudited) | 3 |
| | Condensed Consolidated Balance Sheets at March 31, 2008 and December 31, 2007 | 3 |
| | Condensed Consolidated Statements of Operations for the Three Months ended March | |
| | 31, 2008 and 2007 | 4 |
| | Condensed Consolidated Statement of Stockholders' Equity and Comprehensive Loss for | |
| | the Three Months ended March 31, 2008 | 5 |
| | Condensed Consolidated Statements of Cash Flows for the Three Months ended March | |
| | 31, 2008 and 2007 | 6 |
| | Notes to Condensed Consolidated Financial Statements | 7 |
| Item 2. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 18 |
| Item 3. | Quantitative and Qualitative Disclosures about Market Risk | 34 |
| Item 4. | Controls and Procedures | 34 |
| | | |
| PART II | OTHER INFORMATION | |
| Item 1A. | Risk Factors | 35 |
| Item 6. | <u>Exhibits</u> | 40 |
| | <u>Signatures</u> | 41 |

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

PROGENICS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(amounts in thousands, except for par value and share amounts) (Unaudited)

| | arch 31, | 31 | ecember , 107 |
|--|---------------|----|---------------------|
| Assets | | | |
| Current assets: | | | |
| Cash and cash equivalents | \$ 25,985 | \$ | 10,423 |
| Marketable securities | 79,657 | | 120,000 |
| Accounts receivable | 1,607 | | 1,995 |
| Other current assets | 3,378 | | 3,111 |
| Total current assets | 110,627 | | 135,529 |
| Marketable securities | 49,326 | | 39,947 |
| Fixed assets, at cost, net of accumulated depreciation and amortization | 13,194 | | 13,511 |
| Restricted cash | 553 | | 552 |
| Total assets | \$ 173,700 | \$ | 189,539 |
| | | | |
| Liabilities and Stockholders' Equity | | | |
| Current liabilities: | | | |
| Accounts payable and accrued expenses | \$ 12,696 | \$ | 14,765 |
| Deferred revenue ¾ current | 16,135 | | 17,728 |
| Other current liabilities | 57 | | 57 |
| Total current liabilities | 28,888 | | 32,550 |
| Deferred revenue —long term | 6,626 | | 9,131 |
| Other liabilities | 336 | | 359 |
| Total liabilities | 35,850 | | 42,040 |
| Commitments and contingencies (Note 10) | | | |
| Stockholders' equity: | | | |
| Preferred stock, \$.001 par value; 20,000,000 shares authorized; issued and | | | |
| outstanding—none | | | |
| Common stock, \$.0013 par value; 40,000,000 shares authorized; issued and outstanding- | | | |
| 29,908,993 in 2008 and 29,753,820 in 2007 | 39 | | 39 |
| Additional paid-in capital | 406,950 | | 401,500 |
| Accumulated deficit | (269,531) | | (254,046) |
| Accumulated other comprehensive income | 392 | | 6 |
| Total stockholders' equity | 137,850 | | 147,499 |
| Total liabilities and stockholders' equity | \$ 173,700 | \$ | 189,539 |

The accompanying notes are an integral part of these condensed financial statements.

PROGENICS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(amounts in thousands, except net loss per share)
(Unaudited)

| | For the Three Months Ended | | | |
|---|-------------------------------|----------|----|----------|
| | March 31, | | | • • |
| | | 2008 | | 2007 |
| Revenues: | | | | |
| Research and development from collaborator | \$ | 12,110 | \$ | 15,499 |
| Research grants and contracts | | 2,613 | | 2,119 |
| Product sales | | 39 | | 19 |
| Total revenues | | 14,762 | | 17,637 |
| | | | | |
| Expenses: | | | | |
| Research and development | | 22,790 | | 22,421 |
| License fees ³ / ₄ research and development | | 1,149 | | 750 |
| General and administrative | | 7,152 | | 6,276 |
| Depreciation and amortization | | 1,114 | | 492 |
| Total expenses | | 32,205 | | 29,939 |
| | | | | |
| Operating loss | | (17,443) | | (12,302) |
| | | | | |
| Other income: | | | | |
| Interest income | | 1,958 | | 1,869 |
| Total other income | | 1,958 | | 1,869 |
| | | | | |
| Net loss | \$ | (15,485) | \$ | (10,433) |
| | | | | |
| Net loss per share - basic and diluted | \$ | (0.52) | \$ | (0.40) |
| Weighted-average shares - basic and diluted | | 29,834 | | 26,365 |

The accompanying notes are an integral part of these condensed financial statements.

.

PROGENICS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

FOR THE THREE MONTHS ENDED MARCH 31, 2008

(amounts in thousands) (Unaudited)

| | Common S | tock | Additional Paid-In | Accum Otl AccumulatedCompre | ner | Comprehensive |
|---|----------|-------|-----------------------|-----------------------------------|-------------|------------------|
| | Shares | Amoun | Capital | Deficit Inco | ome Tota | l (Loss) |
| Balance at December 31, 2007 | 29,754 | \$ 39 | 9 \$ 401,500 | \$ (254,046) \$ | 6 \$ 147, | 499 |
| Compensation expense for vesting of share-based payment arrangements | | | 2.042 | | | |
| - O | | | 3,912 | | 3, | 912 |
| Issuance of restricted stock, net of forfeitures | (2) | | | | | |
| Sale of common stock under employee stock purchase plans and exercise of stock options | 157 | | 1,538 | | 1. | 538 |
| Net (loss) | 137 | | 1,556 | | 1, | ,556 |
| 100 (1000) | | | | (15,485) | (15, | 485) \$ (15,485) |
| Net change in unrealized gain on marketable securities | | | | | | 386 386 |
| | | | | | | |
| Balance at March 31, 2008 | 29,909 | \$ 39 | \$ 406,950 | \$ (269,531) \$ | 392 \$ 137, | 850 \$ (15,099) |

The accompanying notes are an integral part of these condensed financial statements.

PROGENICS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands) (Unaudited)

| | Three Mon Marc | |
|--|-------------------|----------------|
| | 2008 | 2007 |
| Cash flows from operating activities: | | |
| Net loss | \$ (15,485) | \$ (10,433) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,114 | 492 |
| Amortization of discounts, net of premiums, on marketable securities | 95 | (49) |
| Noncash expenses incurred in connection with vesting of share-based compensation | | |
| awards | 3,912 | 2,948 |
| Changes in assets and liabilities: | | |
| Decrease in accounts receivable | 388 | |
| (Increase) decrease in other current assets | (267) | 346 |
| (Decrease) increase in accounts payable and accrued expenses | (2,069) | 1,133 |
| Decrease in deferred revenue | (4,098) | (5,272) |
| (Decrease) increase in deferred lease liability | (23) | 1 |
| Net cash used in operating activities | (16,433) | (10,834) |
| Cash flows from investing activities: | | |
| Capital expenditures | (797) | (1,067) |
| Sales of marketable securities | 63,055 | 69,439 |
| Purchase of marketable securities | (31,800) | (52,050) |
| Increase in restricted cash | (1) | (2) |
| Net cash provided by investing activities | 30,457 | 16,320 |
| Cash flows from financing activities: | | |
| Proceeds from the exercise of stock options and sale of Common Stock under the | | |
| Employee Stock Purchase Plans | 1,538 | 2,804 |
| Net cash provided by financing activities | 1,538 | 2,804 |
| Net increase in cash and cash equivalents | 15,562 | 8,290 |
| Cash and cash equivalents at beginning of period | 10,423 | 11,947 |
| Cash and cash equivalents at end of period | \$ 25,985 | \$ 20,237 |

The accompanying notes are an integral part of these condensed financial statements.

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

1. Interim Financial Statements

Progenics Pharmaceuticals, Inc. (the "Company" or "Progenics") is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. The Company's principal programs are directed toward gastroenterology, virology and oncology.

The Company was incorporated in Delaware on December 1, 1986 and commenced principal operations in late 1988. Currently, all of the Company's operations are conducted at the Company's facilities in Tarrytown, New York. The Company's chief operating decision maker reviews financial analyses and forecasts relating to all of the Company's research programs as a single unit and allocates resources and assesses performance of such programs as a whole. The Company operates under a single research and development segment.

The Company's lead product is RELISTORTM (methylnaltrexone bromide). On April 24, 2008 RELISTOR subcutaneous injection was approved by the U.S. Food and Drug Administration (FDA) for sale in the United States for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Progenics' collaboration partner, Wyeth Pharmaceuticals ("Wyeth"), plans to launch the sale of RELISTOR subcutaneous injection in the United States in June 2008.

RELISTOR subcutaneous injection received marketing approval from Health Canada in March 2008 for the treatment of OIC in patients with advanced illness receiving palliative care. A launch of RELISTOR subcutaneous injection sales in Canada is planned by Wyeth for June 2008.

A Positive Opinion for RELISTOR subcutaneous injection was received on April 24, 2008 from the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMEA), for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. Final action by the European Commission on the marketing application to the EMEA is expected by mid-2008.

Marketing applications for RELISTOR subcutaneous injection are also pending in Australia and other countries.

Development and commercialization of RELISTOR is being conducted under a license and co-development agreement ("Collaboration Agreement") between the Company and Wyeth. Under that agreement, the Company (i) has received an upfront payment from Wyeth, (ii) has received, and is entitled to receive further, additional payments as certain developmental milestones for RELISTOR are achieved, (iii) has been and will be reimbursed by Wyeth for expenses the Company incurs in connection with the development of RELISTOR under an agreed-upon development plan and (iv) will receive royalties and commercialization milestone payments. These payments will depend on the successful development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth and the FDA and other regulatory bodies, as well as the outcome of clinical and other testing of RELISTOR. Many of these matters are outside the control of the Company. Manufacturing and commercialization expenses for RELISTOR will be funded by Wyeth.

In May 2007, the Company earned \$9.0 million in milestone payments under its Collaboration Agreement with Wyeth for having made filings seeking marketing approval for RELISTOR subcutaneous injection in the U.S. and Europe. In

April 2008, the Company earned a \$15.0 million milestone payment for the FDA approval of subcutaneous RELISTOR.

The Company and Wyeth are also developing intravenous and oral formulations of RELISTOR.

The Company's other product candidates, including those for treatment of Human Immunodeficiency virus ("HIV") infection, therapy for prostate cancer involving prostate-specific membrane antigen ("PSMA") and treatment of hepatitis C virus ("HCV") infection, are not as advanced in development as RELISTOR, and the Company does not expect any recurring revenues from sales or otherwise with respect to these product candidates in the near term. As a result of Wyeth's agreement to reimburse Progenics for RELISTOR development expenses, the Company is able to devote its current and future resources to its other research and development programs.

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

As a result of its development expenses and other needs, the Company may require additional funding to continue its operations. The Company may enter into a collaboration agreement, or a license or sale transaction, with respect to its product candidates other than RELISTOR. The Company may also seek to raise additional capital through the sale of its common stock or other securities and expects to fund certain aspects of its operations through government grants and contracts.

The Company has had recurring losses. At March 31, 2008, the Company had an accumulated deficit of \$269.5 million and had cash, cash equivalents and marketable securities, including non-current portion, totaling \$155.0 million. The Company expects that cash, cash equivalents and marketable securities at March 31, 2008 will be sufficient to fund current operations beyond one year. During the three months ended March 31, 2008, the Company had a net loss of \$15.5 million and used cash in operating activities of \$16.4 million.

On April 24, 2008, Progenics announced that its Board of Directors had approved a share repurchase program to acquire up to \$15 million of its outstanding common shares, funding for which will come from the \$15 million milestone payment the Company will receive from Wyeth for receiving U.S. marketing approval for RELISTOR. Purchases under the program will be made at the Company's discretion subject to market conditions in the open-market or otherwise, and will be made in accordance with the regulations of the U.S. Securities and Exchange Commission, including Rule 10b-18. The Company has made no commitment to purchase any shares and purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired.

Pending use in its business, the Company's revenues and proceeds of financing activities are held in cash, cash equivalents and marketable securities. Its marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale.

The interim Condensed Consolidated Financial Statements of the Company included in this report have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting primarily of normal recurring accruals, necessary for a fair statement of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. 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 fiscal year ended December 31, 2007. All terms used but not defined elsewhere herein have the meaning ascribed to them in that Annual Report. The year end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

2. Share-Based Payment Arrangements

On January 1, 2007, the Company began to estimate the expected term of stock options granted to employees and officers and directors by using historical data for each of those two groups. The expected term for options granted to the two groups mentioned above was 5.33 and 8 years, respectively in 2008 and 5.25 and 7.5 years, respectively in 2007. The expected term for stock options granted to non-employee consultants was ten years, which was equal to the contractual term of those options. The expected volatility of stock options granted to each group was calculated based

upon the periods of the respective expected terms. The Company has never paid dividends and does not expect to pay dividends in the future. Therefore, the Company's dividend rate is zero. The risk-free rate for periods within the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

The assumptions used by the Company in the Black-Scholes option pricing model to estimate the grant date fair values of stock options granted under the Plans during the three months ended March 31, 2008 and 2007 were as follows:

| | For the Three Months Ended March 31, | | | | |
|--|--------------------------------------|-------------|--|--|--|
| | 2008 | 2007 | | | |
| Expected volatility | 66% – 90% | 55% - 89% | | | |
| Expected dividends | zero | zero | | | |
| Expected term (in years) | 5.33 - 10 | 5.25 - 10 | | | |
| Weighted average expected term (years) | 5.58 | 9.0 | | | |
| Risk-free rate | 3.08% - 3.71% | 4.4% - 4.5% | | | |

During the three months ended March 31, 2008 and 2007, the fair value of shares purchased under the Purchase Plans was estimated on the date of grant in accordance with FASB Technical Bulletin No. 97-1 "Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option," using the same option valuation model used for options granted under the Plans, except that the assumptions noted in the following table were used for the Purchase Plans:

| | For the Three Marc | |
|---------------------|--------------------|----------|
| | 2008 | 2007 |
| Expected volatility | 154% | 40% |
| Expected dividends | zero | zero |
| Expected term | 6 months | 6 months |
| Risk-free rate | 2.74% | 5.1% |

The total fair value of shares under all of the Company's share-based payment arrangements that vested during the three months ended March 31, 2008 and 2007 was \$3.9 million and \$2.9 million, respectively; \$2.0 million and \$1.6 million, respectively, of which was reported as research and development expense and \$1.9 million and \$1.3 million, respectively, of which was reported as general and administrative expense.

No tax benefit was recognized related to such compensation cost during the three months ended March 31, 2008 and 2007 because the Company had a net loss for each of those periods and the related deferred tax assets were fully offset by valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the three months ended March 31, 2008 and 2007.

In applying the treasury stock method for the calculation of diluted earnings per share ("EPS"), amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted earnings per share calculation unless they are anti-dilutive. The Company incurred a

net loss for the three months ended March 31, 2008 and 2007 and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for each of those periods. The Company has made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculation, excluding the impact of pro forma deferred tax assets. This policy decision will apply when the Company has net income.

3. Fair Value Measurements

The Company's available-for-sale investment portfolio consists of marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, and is recorded at fair value in the accompanying Condensed Consolidated Balance Sheets in accordance with Financial Accounting Standards Board ("FASB") Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities." The change in the fair value of these investments is recorded as a component of other comprehensive income.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

Investments consisted of the following:

| | I | March 31, |] | December 31, |
|-------------------------|----|-----------|----|--------------|
| | | 2008 | | 2007 |
| Short-term | | | | |
| Commercial paper | \$ | 78,832 | \$ | 81,170 |
| Auction rate securities | | 825 | | 38,830 |
| Total short-term | | | | |
| investments | | 79,657 | | 120,000 |
| | | | | |
| Long-term | | | | |
| Commercial paper | | 42,409 | | 39,947 |
| Auction rate | | | | |
| securities | | 6,917 | | - |
| Total long-term | | | | |
| investments | | 49,326 | | 39,947 |
| Total investments | \$ | 128,983 | \$ | 159,947 |

The Company adopted FASB Statement No. 159 ("FAS 159") "The Fair Value Option of Financial Assets and Financial Liabilities" effective January 1, 2008, which provides companies with an option to report certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. FAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The objective of FAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. The Company has elected not to apply the fair value option to any of its assets or liabilities.

The Company also adopted FASB Statement No. 157 ("FAS 157") "Fair Value Measurements" effective January 1, 2008 for financial assets and financial liabilities. FAS 157 defines fair value as the price that would be received to sell an asset or would be paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date, and establishes a framework to make the measurement of fair value more consistent and comparable. In accordance with Financial Accounting Standards Board Staff Position (FSP) 157-2, "Effective Date of FASB Statement No. 157," the Company will defer the adoption of FAS 157 for its nonfinancial assets and nonfinancial liabilities, until January 1, 2009. The Company is currently evaluating the impact of FAS 157 for nonfinancial assets and nonfinancial liabilities, and the adoption of this statement is not expected to have a material effect on the Company's financial position or results of operations. The partial adoption of FAS 157 did not have a material impact on the Company's fair value measurements.

FAS 157 established a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed based on market data obtained from sources independent of the reporting entity ("observable inputs") and the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances ("unobservable inputs"). The hierarchy level assigned to each security in our available-for-sale portfolio is based on our assessment of the transparency and reliability of the inputs used in the

valuation of such instrument at the measurement date. The three hierarchy levels are defined as follows:

- Level 1 Valuations based on unadjusted quoted market prices in active markets for identical securities.
- Level 2 Valuations based on observable inputs (other than Level 1 prices), such as quoted prices for similar assets at the measurement date; quoted prices in markets that are not active; or other inputs that are observable, either directly or indirectly.
- Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement, and involve management judgment.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

The following table presents our available-for-sale investments measured at fair value on a recurring basis as of March 31, 2008 classified by the SFAS No. 157 valuation hierarchy (as discussed above):

| | | | Fair Value Measurements at Reporting Date Using | | | | | |
|-------------------------|---------------|---------|---|----------|-----|------------|-----------|----------|
| | Quoted Prices | | | | | | | |
| | | | in | Active | Sig | nificant | | |
| | | | Maı | kets for | (| Other | | ificant |
| | Bal | ance at | Identical | | Obs | Observable | | servable |
| | Ma | rch 31, | 31, Assets Inputs | | | | | puts |
| Description | 2 | 2008 | (Level 1) (1 | | (L | evel 2) | (Level 3) | |
| • | | | | | | | | |
| Money market funds | \$ | 22,192 | \$ | 22,192 | \$ | - | \$ | - |
| Commercial paper | | 121,241 | | - | | 121,241 | | - |
| Auction rate securities | | 7,742 | | - | | - | | 7,742 |
| | | | | | | | | |
| Total | \$ | 151,175 | \$ | 22,192 | \$ | 121,241 | \$ | 7,742 |

At March 31, 2008 the company holds \$7.7 million in auction rate securities that were originally issued with Aaa/AAA credit ratings. Auction rate securities are collateralized long-term instruments that provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined intervals, typically every 7 to 35 days. Beginning in February 2008, auctions failed for certain of the Company's auction rate securities because sell orders exceeded buy orders, and the Company was unable to dispose of those securities at auction. The funds associated with these failed auctions will not be accessible until a successful auction occurs, the issuer calls or restructures the security, the security matures and is paid or a buyer outside the auction process emerges. The fair value of the auction rate securities we hold, includes \$4.0 million of securities collateralized by student loan obligations subsidized by the U.S. government, \$1.8 million of municipal bonds and \$1.9 million of investment company preferred stock, and do not include mortgage-backed instruments. As of March 31, 2008, Progenics has received all scheduled interest payments on these securities, which, in the event of auction failure, are reset according to the contractual terms in the governing instrments.

Progenics continues to monitor the market for auction rate securities and consider its effect (if any) on the fair market value of its investments. If market conditions do not recover, the Company may be required to record additional impairment charges in 2008. Progenics believes it will have the ability to hold any auction rate securities for which auctions fail until the market recovers. It does not anticipate having to sell these securities in order to operate its business. The Company does not believe the carrying values of these auction rate securities are permanently impaired and therefore expects the positions will eventually be liquidated without significant loss.

The valuation of these securities is based on Level 3 unobservable inputs which consist of recommended fair values based on internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. As a result of the estimated fair value, the Company has determined a

temporary impairment in the valuation of these securities of \$0.4 million which is reflected as a part of other comprehensive income on its balance sheet. These securities are held "available for sale" in conformity with FAS 115, "Accounting for Certain Investments in Debt and Equity Securities," and the unrealized loss is included in other comprehensive income in the current period. Due to the uncertainty related to the liquidity in the auction rate security market and therefore when individual positions may be liquidated, the Company has classified \$6.9 million of these auction rate securities as long-term assets on its balance sheet. The Company has classified the remaining \$0.8 million as short-term securities, as an auction rate security was redeemed at par by the issuer in April 2008.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

For those financial instruments with significant Level 3 inputs, the following table summarizes the activity for the period by investment type:

| | Fair Value Measurements Using | | | | |
|---|---------------------------------|-----------|-------|-------|--|
| | Significant Unobservable Inputs | | | | |
| | | (Lev | el 3) | | |
| | Auc | tion Rate | | | |
| Description | Se | curities | | Total | |
| • | | | | | |
| Beginning Balance | \$ | - | \$ | - | |
| Transfers in to Level 3 | | 8,150 | | 8,150 | |
| Total realized/unrealized losses | | | | | |
| Included in earnings | | - | | - | |
| Included in comprehensive income | | (408) | | (408) | |
| Purchases, issuances and settlements | | - | | - | |
| Ending Balance | \$ | 7,742 | \$ | 7,742 | |
| Total amount of unrealized losses for the period | | | | | |
| included in other | | | | | |
| comprehensive loss attributable to the change in | | | | | |
| fair market | | | | | |
| value of related assets still held at the reporting | | | | | |
| date | \$ | (408) | \$ | (408) | |

4. Prepaid Research and Development

On January 1, 2008, the Company adopted Emerging Issues Task Force Issue 07-3 ("EITF 07-3") "Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities." Prior to January 1, 2008, under FASB Statement No. 2, "Accounting for Research and Development Costs," non-refundable advance payments for future research and development activities for materials, equipment, facilities and purchased intangible assets that had no alternative future use were expensed as incurred. Beginning in the quarter ended March 31, 2008, the Company has been capitalizing such non-refundable advance payments and expensing them as the goods are delivered or the related services are performed. EITF 07-3 applies to new contracts entered into after the effective date of January 1, 2008. The impact of applying EITF 07-3 did not have a material impact on the financial position or results of operations for the quarter ended March 31, 2008.

5. Accounts Receivable

| | Marc | March 31, | | December 31, | |
|-------------------------------|------|-----------|----|--------------|--|
| | 20 | 08 | | 2007 | |
| National Institutes of Health | \$ | 1,589 | \$ | 1,956 | |
| Other | | 18 | | 39 | |
| Total | \$ | 1,607 | \$ | 1,995 | |

6. Accounts Payable and Accrued Expenses

Edgar Filing: PROGENICS PHARMACEUTICALS INC - Form 10-Q

| | rch 31, 2008 | De | cember 31, 2007 |
|---|-----------------|----|-----------------|
| Accounts payable | \$ 1,328 | \$ | 1,158 |
| Accrued consulting and clinical trial costs | 8,452 | | 10,848 |
| Accrued payroll and related costs | 1,438 | | 1,489 |
| Legal and professional fees | 1,478 | | 1,127 |
| Other | 0 | | 143 |
| Total | \$ 12,696 | \$ | 14,765 |

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

7. Revenue Recognition

On December 23, 2005, the Company entered into the Collaboration Agreement with Wyeth (collectively, the "Parties") for the purpose of developing and commercializing RELISTOR, the Company's lead investigational drug, for the treatment of opioid-induced side effects, including constipation and post-operative ileus, associated with chronic pain and in patients receiving palliative care. The Collaboration Agreement involves three formulations of RELISTOR: (i) a subcutaneous formulation to be used in patients with opioid-induced constipation, (ii) an intravenous formulation to be used in patients with opioid-induced constipation.

The collaboration is being administered by a Joint Steering Committee and a Joint Development Committee, each with equal representation by the Parties. The Steering Committee is responsible for coordinating the key activities of Wyeth and the Company under the Collaboration Agreement. The Development Committee is responsible for overseeing, coordinating and expediting the development of RELISTOR by the Parties. In addition, a Joint Commercialization Committee was established, composed of representatives of both Wyeth and the Company in number and function according to each of their responsibilities, which is responsible for facilitating open communication between Wyeth and the Company on matters relating to the commercialization of products.

The Company has assessed the nature of its involvement with the Committees. The Company's involvement in the Steering and Development Committees is one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. The Company has combined the committee obligations with the other development obligations and is accounting for these obligations during the development phase as a single unit of accounting. After the period during which Progenics has developmental responsibilities, however, the Company has assessed that the nature of its involvement with the Committees will be a right, rather than an obligation. The Company's assessment is based upon the fact the Company negotiated to be on the Committees as an accommodation for its granting of the license for RELISTOR to Wyeth. Wyeth has been granted by the Company an exclusive license (even as to the Company) to the technology and know-how regarding RELISTOR and has been assigned the agreements for the manufacture of RELISTOR by third parties. During that period, the activities of the Committees will be focused on Wyeth's development and commercialization obligations.

Under the Collaboration Agreement, Progenics granted to Wyeth an exclusive, worldwide license, even as to Progenics, to develop and commercialize RELISTOR. Progenics is responsible for developing the subcutaneous and intravenous formulations in the United States, until the drug formulations receive regulatory approval. Progenics has transferred to Wyeth all existing supply agreements with third parties for RELISTOR and has sublicensed intellectual property rights to permit Wyeth to manufacture or have manufactured RELISTOR, during the development and commercialization phases of the Collaboration Agreement, in both bulk and finished form for all products worldwide. Progenics has no further manufacturing obligations under the Collaboration Agreement. Progenics has and will continue to transfer to Wyeth all know-how, as defined, related to RELISTOR. Based upon the Company's research and development programs, such period will cease upon completion of the Company's development obligations under the Collaboration Agreement.

Wyeth is developing the oral formulation worldwide and the subcutaneous and intravenous formulations outside the U.S. In the event the Joint Steering Committee approves any formulation of RELISTOR other than subcutaneous, intravenous or oral or any other indication for a product using any formulation of RELISTOR, Wyeth will be

responsible for development of such products, including conducting clinical trials and obtaining and maintaining regulatory approval and the Company will receive royalties on all sales of such products.

Wyeth is responsible for the commercialization of the subcutaneous, intravenous and oral products, and any other products developed upon approval by the Joint Steering Committee, throughout the world. Wyeth will pay all costs of commercialization of all products, including manufacturing costs, and will retain all proceeds from the sale of the products, subject to the royalties payable by Wyeth to the Company. Decisions with respect to commercialization of any products developed under the Collaboration Agreement will be made solely by Wyeth.

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

Wyeth granted to Progenics an option (the "Co-Promotion Option") to enter into a Co-Promotion Agreement to co-promote any of the products developed under the Collaboration Agreement, subject to certain conditions. The Company may exercise this option on an annual basis. The Company has not exercised the option in connection with the initial commercialization of RELISTOR, and as of March 31, 2008 has not determined when it will exercise it, if at all. The extent of the Company's co-promotion activities and the fee that the Company will be paid by Wyeth for these activities will be established if, as and when the Company exercises its option. Wyeth will record all sales of products worldwide (including those sold by the Company, if any, under a Co-Promotion Agreement). Wyeth may terminate any Co-Promotion Agreement if a top 15 pharmaceutical company acquires control of Progenics. Progenics' potential right to commercialize any product, including its Co-Promotion Option, is not essential to the usefulness of the already delivered products or services (i.e., Progenics' development obligations) and Progenics' failure to fulfill its co-promotion obligations would not result in a full or partial refund of any payments made by Wyeth to Progenics or reduce the consideration due to Progenics by Wyeth or give Wyeth the right to reject the products or services previously delivered by Progenics.

The Company is recognizing revenue in connection with the Collaboration Agreement under the Securities and Exchange Commission's Staff Accounting Bulletin No. 104 ("SAB 104") "Revenue Recognition" and will apply the Substantive Milestone Method. In accordance with the Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21") "Accounting for Revenue Arrangements with Multiple Deliverables," all of the Company's deliverables under the Collaboration Agreement, consisting of granting the license for RELISTOR, transfer of supply contracts with third party manufacturers of RELISTOR, transfer of know-how related to RELISTOR development and manufacturing, and completion of development for the subcutaneous and intravenous formulations in the U.S., represent one unit of accounting since none of those components have standalone value to Wyeth prior to regulatory approval of at least one product; that unit of accounting comprises the development phase, through regulatory approval, for the subcutaneous and intravenous formulations in the U.S.

Within five business days of execution of the Collaboration Agreement, Wyeth made a non-refundable, non-creditable upfront payment of \$60 million, for which the Company deferred revenue at December 31, 2005. Subsequently, the Company is recognizing revenue related to the upfront license payment over the period during which the performance obligations, noted above, are being performed using the proportionate performance method. The Company expects that period to extend through 2009. The Company is recognizing revenue using the proportionate performance method since it can reasonably estimate the level of effort required to complete its performance obligations under the Collaboration Agreement with Wyeth and such performance obligations are provided on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Under the proportionate performance method, revenue related to the upfront license payment is recognized in any period as the percent of actual effort expended in that period relative to expected total effort. The total effort expected is based upon the most current budget and development plan which is approved by both the Company and Wyeth and includes all of the performance obligations under the arrangement. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for the Company to complete its performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. Since the Company has no obligation to develop the subcutaneous and intravenous formulations of RELISTOR outside the U.S. or the oral formulation at all and has no significant commercialization obligations for any product, recognition of revenue for the upfront payment is not required during those periods, if they extend beyond the period of the Company's development obligations. If Wyeth terminates the Collaboration Agreement in accordance with its terms, the Company will

recognize any unamortized remainder of the upfront payment at the time of the termination.

The amounts of the upfront license payment that the Company recognized as revenue for each fiscal quarter prior to the third quarter of 2007 were based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amounts of revenue recognized in those periods. During the third quarter of 2007, however, the estimate of the Company's total remaining effort to complete its development obligations was increased significantly based upon a revised development budget approved by both the Company and Wyeth. As a result, the period over which the Company's obligations will extend, and over which the upfront payment will be amortized, was extended from the end of 2008 to the end of 2009. Consequently, the amount of revenue recognized from the upfront payment in the first quarter of 2008 declined relative to that in the comparable period of 2007.

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

Beginning in January 2006, costs for the development of RELISTOR incurred by Wyeth or the Company are being paid by Wyeth. Wyeth has the right once annually to engage an independent public accounting firm to audit expenses for which the Company has been reimbursed during the prior three years. If the accounting firm concludes that any such expenses have been understated or overstated, a reconciliation will be made. The Company is recognizing as research and development revenue from collaborator, amounts received from Wyeth for reimbursement of the Company's development expenses for RELISTOR as incurred under the development plan agreed to between the Company and Wyeth. In addition to the upfront payment and reimbursement of the Company's development costs, Wyeth has made or will make the following payments to the Company: (i) development and sales milestones and contingent payments, consisting of defined non-refundable, non-creditable payments, totaling \$356.5 million, including clinical and regulatory events and combined annual worldwide net sales, as defined, and (ii) sales royalties during each calendar year during the royalty period, as defined, based on certain percentages of net sales in the U.S. and worldwide. Upon achievement of defined substantive development milestones by the Company for the subcutaneous and intravenous formulations in the U.S., the milestone payments will be recognized as revenue. Recognition of revenue for developmental contingent events related to the subcutaneous and intravenous formulations outside the U.S. and for the oral formulation, which are the responsibility of Wyeth, will be recognized as revenue when Wyeth achieves those events, if they occur subsequent to completion by the Company of its development obligations, since Progenics would have no further obligations related to those products. Otherwise, if Wyeth achieves any of those events before the Company has completed its development obligations, recognition of revenue for the Wyeth contingent events will be recognized over the period from the effective date of the Collaboration Agreement to the completion of the Company's development obligations. All sales milestones and royalties will be recognized as revenue when earned.

During the three months ended March 31, 2008 and 2007, the Company recognized \$3.2 million and \$5.0 million, respectively, of revenue from the \$60 million upfront payment and \$8.9 million and \$10.5 million, respectively, as reimbursement for its out-of-pocket development costs, including its labor costs. In March 2007, the Company earned \$9.0 million in milestone payments upon the submission and approval for review of applications for marketing in the U.S. and European Union of the subcutaneous formulation of RELISTOR in patients receiving palliative care. The Company considered those milestones to be substantive based on (i) the significant degree of risk, at the inception of the Collaboration Agreement, related to the conduct and successful completion of clinical trials and, therefore, of not achieving the milestones; (ii) the amount of the payment received relative to the significant costs incurred since inception of the Collaboration Agreement and amount of effort expended to achieve the milestones; and (iii) the passage of ten and seventeen months, respectively, from inception of the Collaboration Agreement to the achievement of those milestones. Therefore, the Company recognized the milestone payments as revenue in the respective periods in which the milestones were earned. As of March 31, 2008, relative to the \$60 million upfront license payment received from Wyeth, the Company has recorded \$14.9 million as short-term deferred revenue and \$6.6 million as long-term deferred revenue, which is expected to be recognized as revenue through 2009. In addition, at March 31, 2008, the Company recorded \$1.2 million of short term deferred revenue related to payments we have received from Wyeth for development costs.

The Collaboration Agreement extends, unless terminated earlier, on a country-by-country and product-by-product basis, until the last to expire royalty period, as defined, for any product. Progenics may terminate the Collaboration Agreement at any time upon 90 days of written notice to Wyeth (30 days in the case of breach of a payment obligation) upon material breach that is not cured. Wyeth may, with or without cause, following the second anniversary of the first commercial sale, as defined, of the first commercial product in the U.S., terminate the

Collaboration Agreement by providing Progenics with at least 360 days prior written notice of such termination. Wyeth may also terminate the agreement (i) upon 30 days written notice following one or more serious safety or efficacy issues that arise, as defined, and (ii) at any time, upon 90 days written notice of a material breach that is not cured by Progenics. Upon termination of the Collaboration Agreement, the ownership of the license the Company granted to Wyeth will depend on the party that initiates the termination and the reason for the termination.

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

8. Net Loss Per Share

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted-average number of common shares outstanding during the respective periods. For the three months ended March 31, 2008 and 2007, the Company reported a net loss and, therefore, potential common shares were not included since such inclusion would have been anti-dilutive. The calculations of net loss per share, basic and diluted, are as follows:

| | Weighted | | | | |
|-----------------------------------|----------|-----------|---------------|-----------|--|
| | Average | | | | |
| | Common | | | | |
| | Net Loss | | Shares | Per Share | |
| | (Nı | imerator) | (Denominator) | Amount | |
| Three months ended March 31, 2008 | | | | | |
| Basic and Diluted | \$ | (15,485) | 29,834 | \$ (0.52) | |
| Three months ended March 31, 2007 | | | | | |
| Basic and Diluted | \$ | (10,433) | 26,365 | \$ (0.40) | |

For the three months ended March 31, 2008 and 2007, potential common shares, which have been excluded from diluted per share amounts because their effect would have been anti-dilutive, include the following:

| Three Months Ended March 31, | | | | | |
|------------------------------|-----------------------------------|---|---|--|--|
| 2008 | | | 2007 | | |
| Weighted | V | Veighted | Weighted | Weighted | |
| Average | A | Average | Average | Average | |
| Number | Exe | rcise Price | Number | Exercise Price | |
| | | | | | |
| 4,726 | \$ | 18.12 | 4,6899 | \$ 16.77 | |
| 525 | | | 395 | | |
| 5,251 | | | 5,084 | | |
| | Average Number 4,726 525 | Weighted Average Number Exe 4,726 \$ 525 | Weighted Weighted Average Number Exercise Price 4,726 \$ 18.12 525 | Weighted Weighted Weighted Average Average Number Exercise Price Number 4,726 \$ 18.12 4,6895 525 395 | |

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. The Company's comprehensive loss includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. For the three months ended March 31, 2008 and 2007, the components of comprehensive loss were:

| | Three Months Ended | | | |
|----------------------------------|--------------------|-----------|----|----------|
| | | March 31, | | |
| | | 2008 | | 2007 |
| Net loss | \$ | (15,485) | \$ | (10,433) |
| Change in net unrealized gain on | | | | |
| marketable securities | | 386 | | 79 |
| Comprehensive loss | \$ | (15,099) | \$ | (10,354) |

10. Commitments and Contingencies

In the ordinary course of its business, the Company enters into agreements with third parties that include indemnification provisions which, in its judgment, are normal and customary for companies in its industry sector. These agreements are typically with business partners, clinical sites and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company's products or product candidates, use of such products or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is not limited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, the Company has no liabilities recorded for these provisions as of March 31, 2008.

Table of Contents

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited) (amounts in thousands, except per share amounts or unless otherwise noted)

11. Impact of Recently Issued Accounting Standards

In March 2008, the Financial Accounting Standards Board ("FASB") issued SFAS No. 161 ("FAS 161") "Disclosures about Derivative Instruments and Hedging Activities – an amendment to FASB Statement No. 133," which is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (i) how and why an entity uses derivative instruments; (ii) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations; and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. The Company does not expect the impact of the adoption of FAS 161 to have a material effect on its financial position or results of operations.

Table of Contents

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

Special Note Regarding Forward-Looking Statements

Certain statements in this Quarterly Report on Form 10-Q constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements contained herein that are not statements of historical fact may be forward-looking statements. When we use the words 'anticipates,' 'plans,' 'expects' and similar expressions, it is identifying forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or industry results, to be materially different from any expected future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the risks associated with our dependence on Wyeth to fund and to conduct clinical testing, to make certain regulatory filings and to manufacture and market products containing methylnaltrexone, the uncertainties associated with product development, the risk that clinical trials will not commence, proceed or be completed as planned, the risk that our product candidates will not receive marketing approval from regulators, the risks and uncertainties associated with the dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of our failure to have satisfied performance milestones, the risk that product candidates that appear promising in early clinical trials are later found not to work effectively or are not safe, the risk that we may not be able to manufacture commercial quantities of our products, the risk that our products, if approved for marketing, do not gain sufficient market acceptance to justify development and commercialization costs, the risk that we will not be able to obtain funding necessary to conduct our operations, the uncertainty of future profitability and other factors set forth more fully in our Annual Report on Form 10-K for the year ended December 31, 2007 and in this Form 10-Q, including those described under the caption Risk Factors, and other periodic filings with the U.S. Securities and Exchange Commission, or SEC, to which investors are referred for further information.

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this Form 10-Q as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Overview

General

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward gastroenterology, virology and oncology. We commenced principal operations in late 1988, and since that time we have been engaged primarily in research and development efforts, development of our manufacturing capabilities, establishment of corporate collaborations and raising capital. We do not currently derive revenue from any commercial products. In order to commercialize the principal products that we have under development, we have been and continue to be required to address a number of technological and clinical challenges and comply with comprehensive regulatory requirements.

Gastroenterology

Our lead product is RELISTORTM (methylnaltrexone bromide). On April 24, 2008 RELISTOR subcutaneous injection was approved by the U.S. Food and Drug Administration ("FDA") for sale in the United States for the treatment of

opioid-induced constipation ("OIC") in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Our collaboration partner, Wyeth Pharmaceuticals ("Wyeth"), plans to launch the sale of RELISTOR subcutaneous injection in the United States in June 2008.

RELISTOR subcutaneous injection received marketing approval from Health Canada in March 2008 for the treatment of OIC in patients with advanced illness receiving palliative care. A launch of RELISTOR subcutaneous injection sales in Canada is planned by Wyeth for June 2008.

A Positive Opinion for RELISTOR subcutaneous injection was received on April 24, 2008 from the Committee for Medicinal Products for Human Use ("CHMP"), the scientific committee of the European Medicines Agency ("EMEA"), for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. Final action by the European Commission on the marketing application to the EMEA is expected by mid-2008.

Table of Contents

Marketing applications for RELISTOR subcutaneous injection are also pending in Australia and other countries.

Development and commercialization of RELISTOR is being conducted under a license and co-development agreement ("Collaboration Agreement") between us and Wyeth. Under that agreement, we (i) have received an upfront payment from Wyeth, (ii) have received, and are entitled to receive further, additional payments as certain developmental milestones for RELISTOR are achieved, (iii) have been and will be reimbursed by Wyeth for expenses we incur in connection with the development of RELISTOR under an agreed-upon development plan and (iv) will receive royalties and commercialization milestone payments. These payments will depend on the successful development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth and the FDA and other regulatory bodies, as well as the outcome of clinical and other testing of RELISTOR. Many of these matters are outside our control. Manufacturing and commercialization expenses for RELISTOR will be funded by Wyeth.

In May 2007, we earned \$9.0 million in milestone payments under our Collaboration Agreement with Wyeth for having made filings seeking marketing approval for RELISTOR subcutaneous injection in the U.S. and Europe. In April 2008, we earned a \$15.0 million milestone payment for the FDA approval of subcutaneous RELISTOR.

We are also developing, in collaboration with Wyeth, an intravenous formulation of RELISTOR for the management of post-operative ileus ("POI"), a temporary impairment of the gastrointestinal tract function. Development of the intravenous formulation of RELISTOR for POI has been granted "Fast Track" status from the FDA, which facilitates development and expedites regulatory review of drugs intended to address an unmet medical need for serious or life-threatening conditions.

We and Wyeth have conducted two global pivotal phase 3 clinical trials to evaluate the safety and efficacy of intravenous RELISTOR for the treatment of POI in patients recovering from segmental colectomy surgical procedures. In October 2006, we earned a \$5.0 million milestone payment under the Collaboration Agreement in connection with the initiation of the first phase 3 clinical trial. In October 2007, a third phase 3 intravenous RELISTOR study, being conducted by Wyeth, was initiated in individuals with POI following a ventral hernia repair via laparotomy or laparoscopy.

In March 2008, we reported that preliminary results from the phase 3 segmental colectomy clinical trial conducted by Wyeth showed that treatment did not achieve the primary end point of the study: a reduction in time to recovery of gastrointestinal function (i.e., time to first bowel movement) as compared to placebo. The study also did not show that secondary measures of surgical recovery, including time to discharge eligibility, were superior to placebo. We and Wyeth are conducting the necessary analyses to determine greater clarity regarding the outcome of this clinical study, whose preliminary findings are inconsistent with results demonstrated in our previous phase 2 study of intravenous methylnaltrexone for the management of postoperative ileus. We are leading the second phase 3 trial of intravenous methylnaltrexone for management of POI, which is similar in design to the Wyeth study, and expect results of that trial to be reported by midyear 2008.

We and Wyeth are also developing an oral formulation of RELISTOR for the treatment of OIC in patients with chronic pain.

In March 2007, Wyeth began clinical testing of a new oral formulation of methylnaltrexone for the treatment of OIC, and in July 2007 we and Wyeth announced positive preliminary results from this phase 1 clinical trial. In October 2007, we and Wyeth announced the initiation of two four-week phase 2 clinical trials to evaluate daily dosing of this formulation and a different oral formulation in individuals with chronic, non-malignant pain who are being treated with opioids and are experiencing OIC. These studies are designed to evaluate these oral formulations separately. We and Wyeth plan to assess the safety and dose-response of oral methylnaltrexone as measured by the occurrence of

spontaneous bowel movements during the treatment period. We expect the studies to assist in determining the formulation and doses to be advanced into phase 3 studies.

At inception of the Collaboration Agreement, Wyeth paid to us a \$60 million non-refundable upfront payment. Wyeth has made \$14.0 million in milestone payments since that time and is obligated to make up to \$342.5 million in additional payments to us upon the achievement of milestones and contingent events in the development and commercialization of RELISTOR. Costs for the development of RELISTOR incurred by Wyeth or us starting January 1, 2006 are paid by Wyeth. We are being reimbursed for our out-of-pocket development costs by Wyeth and receive reimbursement for our efforts based on the number of our full time equivalent employees ("FTE"s) devoted to the development project. Wyeth has the right once annually to engage an independent public accounting firm to audit expenses for which we have been reimbursed during the prior three years. If the accounting firm concludes that any such expenses have been understated or overstated, a reconciliation will be made. Wyeth is obligated to pay to us royalties on the sale of RELISTOR by Wyeth throughout the world during the applicable royalty periods.

Table of Contents

In January 2006, we began recognizing revenue from Wyeth for reimbursement of our development expenses for RELISTOR as incurred during each quarter under the development plan agreed to by us and Wyeth. We also began recognizing revenue for a portion of the \$60 million upfront payment we received from Wyeth, based on the proportion of the expected total effort for us to complete our development obligations, as reflected in the most recent development plan and budget approved by us and Wyeth, that was actually performed during that quarter.

Virology

In the area of virology, we are developing viral-entry inhibitors for Human Immunodeficiency Virus ("HIV"), the virus that causes AIDS, and Hepatitis C virus infection ("HCV"). These inhibitors are molecules designed to inhibit a virus' ability to enter certain types of immune cells and liver cells. In May 2007, we announced positive results from a phase 1b trial of an intravenous formulation of our monoclonal antibody, PRO 140, in HIV-infected individuals. We are also investigating a subcutaneous formulation of PRO 140 with the goal of developing a long-acting, self-administered therapy for HIV infection. In January 2008, we initiated the phase 2 clinical program for PRO 140, which will involve both the intravenous and subcutaneous formulations. We are also engaged in research regarding a vaccine against HIV infection.

Oncology

In the area of prostate cancer, we are developing a human monoclonal antibody-drug conjugate, consisting of a selectively targeted cytotoxic antibody directed against prostate specific membrane antigen ("PSMA"), a protein found on the surface of prostate cancer cells. We are also developing vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are conducted through our wholly owned subsidiary, PSMA Development Company LLC ("PSMA LLC"), which prior to April 2006 was a joint venture with Cytogen Corporation ("Cytogen").

In the second quarter of 2007, we discontinued our GMK melanoma vaccine program. An independent data monitoring committee recommended that treatment in the European-based phase 3 trial, which began in 2001, be stopped because lack of efficacy was observed after an interim analysis. We have subsequently terminated our license agreement with Memorial Sloan-Kettering Cancer Center relating to this program.

Table of Contents

Results of Operations (amounts in thousands)

Revenues:

Our sources of revenue during the three months ended March 31, 2008 and 2007 included our collaboration with Wyeth, which was effective on January 1, 2006, our research grants and contracts from the NIH and, to a small extent, our sale of research reagents.

| | Three Months Ended March 31, | | | | |
|------------------------------|------------------------------|-----------|-------------------|--|--|
| Sources of Revenue | 2008 | 2007 | Percent Change | | |
| Research from | ¢ 12 110 | ¢ 15 400 | (2207) | | |
| collaborator | \$ 12,110 | \$ 15,499 | (22%) | | |
| Research grants and contract | 2,613 | 2,119 | 23 % | | |
| Product sales | 39 | 19 | 105% | | |
| Total | \$ 14,762 | \$ 17,637 | (16%) | | |

Research revenue from collaborator

Research revenue from collaborator relates to our Collaboration Agreement with Wyeth. During the three months ended March 31, 2008 and 2007, we recognized \$12,110 and \$15,499, respectively, of revenue from Wyeth, including \$3,234 and \$4,988, respectively, of the \$60,000 upfront payment we received upon entering into our collaboration in December 2005 and \$8,876 and \$10,511, respectively, as reimbursement of our development expenses, including our labor costs. From the inception of the Collaboration Agreement through March 31, 2008, we recognized \$38,443 of revenue from the \$60,000 upfront payment, \$83,537 as reimbursement for our out-of-pocket development costs, including our labor costs and a total of \$14,000 for non-refundable milestone payments.

We recognize a portion of the upfront payment in a reporting period in accordance with the proportionate performance method, which is based on the percentage of actual effort performed on our development obligations in that period relative to total effort expected for all of our performance obligations under the arrangement, as reflected in the most recent development plan and budget approved by Wyeth and us. During the third quarter of 2007, a revised budget was approved, which extended our performance period to the end of 2009 and, thereby, decreased the amount of revenue we are recognizing in each reporting period. As a result, the amount of revenue recognized from the upfront payment in the first quarter of 2008 declined by \$1,754 as compared to the first quarter of 2007.

Reimbursement of development costs, including our labor costs, is recognized as revenue as the costs are incurred under the development plan agreed to by us and Wyeth. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (i) the milestone payment is non-refundable; (ii) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved in achieving the milestone, (iv) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (v) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment. We have analyzed the facts and circumstances of the three milestones achieved since inception of the Collaboration Agreement with Wyeth and believe that they met those criteria for revenue recognition upon achievement of the respective milestones. See Critical Accounting Policies –Revenue Recognition, below.

Research grants and contract

Revenues from research grants and contract from the NIH increased to \$2,613 for the three months ended March 31, 2008 from \$2,119 for the three months ended March 31, 2007; \$2,093 and \$1,296 from grants and \$520 and \$823 from the contract awarded to us by the NIH in September 2003 (the "NIH Contract") for the three months ended March 31, 2008 and 2007, respectively. The increase in grant revenue resulted from fewer reimbursable expenses in 2007 than in 2008 on new and continuing grants. Offsetting this increase was decreased activity under the NIH Contract. The NIH Contract provides for the development of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. Funding under the NIH Contract provides for pre-clinical research, development and early clinical testing. These funds are being used principally in connection with our ProVax HIV vaccine program. The NIH Contract originally provided for up to \$28.6 million in funding to us, subject to annual funding approvals and compliance with its terms, over five years. The total of our approved award under the NIH Contract through September 2008 is \$15.5 million. Funding under this contract includes the payment of an aggregate of \$1.6 million in fees, subject to achievement of specified milestones. Through March 31, 2008, we had recognized revenue of \$13.8 million from this contract, including \$180,000 for the achievement of two milestones. We have recently been informed by the NIH that it has decided not to fund this Contract beyond September 2008. To continue to develop the HIV vaccine after that time, therefore, we will need to provide funding on our own or obtain new governmental or other funding. If we choose not to provide our own or cannot secure governmental or other funding, we will discontinue this project.

Table of Contents

Product sales

Revenues from product sales increased to \$39 for the three months ended March 31, 2008 from \$19 for the three months ended March 31, 2007. We received more orders for research reagents during 2008.

Expenses:

Research and Development Expenses:

Research and development expenses include scientific labor, supplies, facility costs, clinical trial costs, product manufacturing costs and license fees. Research and development expenses increased to \$23,939 for the three months ended March 31, 2008 from \$23,171 for the three months ended March 31, 2007, as follows:

| | Three Months Ended March 31, | | |
|------------------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Salaries and benefits (cash) | \$6,559 | \$5,524 | 19% |

The increase was due to company-wide compensation increases and an increase in average headcount to 200 from 180 for the three months ended March 31, 2008 and 2007, respectively, in the research and development, manufacturing and clinical departments.

| | Three Months Ended March 31, | | |
|-------------------------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Share-based compensation (non-cash) | \$2,012 | \$1,615 | 25% |

The amount of non-cash compensation expense increases/decreases commensurate with headcount levels and is expected to fluctuate in the future as such levels change. (See Critical Accounting Policies – Share-Based Payment Arrangements, below).

| | Three Months Ended March 31, | | |
|----------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Clinical trial costs | \$4,863 | \$4,649 | 5% |

Increase primarily related to HIV (\$769) and RELISTOR (\$363), due to increased PRO 140 and methylnaltrexone clinical trial activities in the 2008 period, respectively. These increases were partially offset by decreases in RELISTOR (\$896), due to regulatory filing fees incurred in the first quarter of 2007, but not in 2008, related to the subcutaneous formulation, Cancer (\$21) due to termination of the GMK study in the second quarter of

2007, and Other projects (\$1). During the remainder of 2008, clinical trial costs are expected to decrease as clinical trials of RELISTOR conclude and we continue the phase 2 trial of PRO 140.

| | Three Months Ended March 31, | | |
|---------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Laboratory supplies | \$1,483 | \$1,657 | (11%) |

Decrease in RELISTOR (\$182), due to purchase of less RELISTOR drug in the 2008 period than in the 2007 period and Cancer (\$22), due to decrease in basic research in 2008. The decreases were partially offset by increases in Other projects (\$28) and HIV-related costs (\$2). Laboratory supply costs for HIV, Cancer and Other projects related costs are expected to increase during the remainder of 2008.

Table of Contents

| | Three Months Ended March 31, | | |
|---|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Contract manufacturing and subcontractors | \$4,666 | \$6,094 | (23%) |

Decrease in Cancer (\$2,068), primarily due to contract manufacturing expenses for PSMA in the first quarter of 2007, but not in 2008, partially offset by increases in Other projects (\$395), HIV (\$220) and RELISTOR (\$25). These expenses are related to the conduct of clinical trials, including manufacture by third parties of drug materials, testing, analysis, formulation and toxicology services, and vary as the timing and level of such services are required. We expect these costs to increase during the remainder of 2008 as we expand our clinical trials for PRO 140, PSMA and Other projects, while costs for RELISTOR are expected to be similar to those in 2007.

| | | Three Months Ended March 31, | |
|-------------|---------|------------------------------|-------------------|
| | 2008 | 2007 | Percent Change |
| Consultants | \$1,615 | \$1,571 | 3% |

Increases in Cancer (\$276), Other projects (\$124) and HIV (\$94), partially offset by a decrease in RELISTOR (\$450). These expenses are related to the monitoring of clinical trials as well as the analysis of data from completed clinical trials and vary as the timing and level of such services are required. During the remainder of 2008, consultant expenses are expected to change approximately proportionately with spending levels for all of our research and development programs.

| | | Three Months Ended March 31, | |
|--------------|---------|------------------------------|-------------------|
| | 2008 | 2007 | Percent Change |
| License fees | \$1,149 | \$750 | 53% |

Increase primarily related to payments in the 2008 period (but not in the 2007 period) related to our HIV program (\$1,000) and RELISTOR (\$10), partially offset by a decrease in Cancer (\$611) related to payments to Cytogen.

| | Three Mor | | |
|--------------------------|-----------|---------|-------------------|
| | 2007 | 2007 | Percent Change |
| Other operating expenses | \$1,592 | \$1,311 | 21% |

Increase primarily due to expenses related to rent (\$262), facilities (\$10) and other operating expenses (\$74), partially offset by decreases in seminar costs (\$22), travel (\$17) and insurance (\$26). During the remainder of 2008, operating expenses are expected to increase over those of 2007, due to higher rent and facility expenses.

A major portion of our spending has been, and we expect will continue to be, associated with RELISTOR, although beginning in 2006, Wyeth has been reimbursing us for development expenses we incur related to RELISTOR under the development plan agreed to between us and Wyeth.

General and Administrative Expenses:

General and administrative expenses increased to \$7,152 for the three months ended March 31, 2008 from \$6,276 for the three months ended March 31, 2007, as follows:

| | Three Months Ended March 31, | | |
|------------------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Salaries and benefits (cash) | \$2,258 | \$1,958 | 15% |

Increase due to compensation increases and an increase in average headcount to 50 from 42 in the general and administrative departments for the three months ended March 31, 2008 and 2007, respectively.

Table of Contents

| | Three Months Ended March 31, | | |
|-------------------------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Share-based compensation (non-cash) | \$1,900 | \$1,333 | 43% |

The amount of non-cash compensation expense increases/decreases commensurate with headcount levels and is expected to fluctuate in the future as such levels change (see Critical Accounting Policies – Share-Based Payment Arrangements, below).

| | Three Months Ended March 31, | | |
|----------------------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Consulting and professional fees | \$1,870 | \$1,840 | 2% |

Increase due primarily to increases in legal and patent fees (\$60), recruiting (\$38) and other miscellaneous costs (\$44). The increases were partially offset by decreases in consulting fees (\$19) and audit and tax fees (\$93).

| | Three Months Ended March 31, | | |
|--------------------------|------------------------------|---------|-------------------|
| | 2008 | 2007 | Percent Change |
| Other operating expenses | \$1,124 | \$1,145 | (2%) |

Decrease in investor relations (\$54), insurance (\$25), travel (\$10) and other operating expenses (\$16), which was partially offset by an increase in rent (\$84) due to higher rent and facility costs.

We expect general and administrative expenses during the remainder of 2008 to remain at approximately 2007 levels.

Depreciation and Amortization:

| | Three Mon Marcl | | |
|-------------------------------|--------------------|-------|-------------------|
| | 2008 | 2007 | Percent Change |
| Depreciation and Amortization | \$1,114 | \$492 | 126% |

Depreciation expense increased to \$1,114 for the three months ended March 31, 2008 from \$492 for the three months ended March 31, 2007, due to purchases of capital assets and additional leasehold improvements made after March

31, 2007.

Other Income:

| | | Three Months Ended March 31, | | | |
|--------------|---------|------------------------------|-------------------|--|--|
| | 2008 | 2007 | Percent Change | | |
| Other Income | \$1,958 | \$1,869 | 5% | | |

Interest income increased to \$1,958 for the three months ended March 31, 2008 from \$1,869 for the three months ended March 31, 2007. Interest income, as reported, is primarily the result of investment income from our marketable securities, increased by the amortization of premiums we paid or decreased by the amortization of discounts we received for those marketable securities. For the three months ended March 31, 2008 and 2007, investment income increased to \$2,053 from \$1,820, respectively, due to a higher average balance of cash equivalents and marketable securities in 2008 than in 2007. Amortization of discounts net of premiums, which is included in interest income, decreased to (\$95) from \$49 for the three months ended March 31, 2008 and 2007, respectively.

Net Loss:

Our net loss was \$15,485 for the three months ended March 31, 2008 and \$10,433 for the three months ended March 31, 2007.

Table of Contents

Liquidity and Capital Resources

Overview

We have to date generated no meaningful amounts of product revenue, and consequently we have relied principally on external funding to finance our operations. We have funded our operations since inception primarily through private placements of equity securities, payments received under collaboration agreements, public offerings of common stock, funding under government research grants and contracts, interest on investments, the proceeds from the exercise of outstanding options and warrants and the sale of our common stock under our Employee Stock Purchase Plans. At March 31, 2008, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$155.0 million compared with \$170.4 million at December 31, 2007. Our existing cash, cash equivalents and marketable securities at March 31, 2008 are sufficient to fund current operations for at least one year. Our cash flow from operating activities was negative for the three months ended March 31, 2008 and 2007 due primarily to the excess of expenditures on our research and development programs and general and administrative costs related to those programs over cash received from collaborators and government grants and contracts to fund such programs, as described below.

Sources of Cash

Operating Activities. Our current collaboration with Wyeth provided us with a \$60 million upfront payment in December 2005. In addition, since January 2006, Wyeth has been reimbursing us for development expenses we incur related to RELISTOR under the development plan agreed to between us and Wyeth, which is currently expected to continue through 2009. For the three months ended March 31, 2008 and 2007, we received \$8.9 million and \$10.5 million, respectively, of reimbursement of our development costs. Since inception of the Collaboration Agreement, Wyeth has made \$14.0 million in milestone payments upon the achievement of certain events which are specified in the Collaboration Agreement. In May 2007, we earned \$9.0 million of milestone payments related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of RELISTOR for the treatment of opioid-induced constipation in patients receiving palliative care in the U.S. and the European Union. Approval of that application resulted in our earning a \$15.0 million milestone payment from Wyeth under the Collaboration Agreement, which we will recognize in the second quarter of 2008. Wyeth has also submitted applications for the marketing of this product in Australia and Canada, the latter of which was approved in March 2008. In October 2006, we earned a \$5.0 million milestone payment in connection with the start of a phase 3 clinical trial of intravenous RELISTOR for the treatment of post-operative ileus. Wyeth is obligated to make up to \$342.5 million in additional payments to us upon the achievement of milestones and other contingent events in the development and commercialization of RELISTOR. Wyeth is also responsible for all commercialization activities related to RELISTOR products. We will receive royalty payments from Wyeth as the product is sold in the various countries where marketing approval has been obtained. We will also receive royalty payments upon the sale of all other products developed under the Collaboration Agreement.

The funding by Wyeth of our development costs for RELISTOR generally enhances our ability to devote our current and future resources to our other research and development programs. We may also enter into collaboration agreements with respect to other of our product candidates. We cannot forecast with any degree of certainty, however, which products or indications, if any, will be subject to future collaborative arrangements, or how such arrangements would affect our capital requirements. The consummation of other collaboration agreements would further allow us to advance other projects with our current funds.

In September 2003, we were awarded a contract by the NIH to develop a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. Funding under the NIH Contract provided for pre-clinical research, development and early clinical testing. These funds are being used principally in

connection with our ProVax HIV vaccine program. The NIH Contract originally provided for up to \$28.6 million in funding to us, subject to annual funding approvals and compliance with its terms, over five years. The total of our approved award under the NIH Contract through September 2008 is \$15.5 million. Funding under this contract includes the payment of an aggregate of \$1.6 million in fees, subject to achievement of specified milestones. Through March 31, 2008, we had recognized revenue of \$13.8 million from this contract, including \$180,000 for the achievement of two milestones. We have recently been informed by the NIH that it has decided not to fund this contract beyond September 2008. To continue to develop the HIV vaccine after that time, therefore, we will need to provide funding on our own or obtain new government or other funding. If we choose not to provide our own or cannot secure governmental or other funding, we will discontinue this project.

Table of Contents

We have also been awarded grants from the NIH, which provide ongoing funding for a portion of our virology and cancer research programs. Among those grants were an aggregate of \$4.4 million in grants made in 2006 and 2007, which extend over two- and three-year periods. Two awards were made during 2005, which provide for up to \$3.0 million and \$9.7 million in support of our HCV research program and PRO 140 HIV development program, respectively, to be awarded over a three year and a three and a half year period, respectively. Funding under all of our NIH grants is subject to compliance with their terms, and is subject to annual funding approvals. For the three months ended March 31, 2008 and 2007, we recognized \$2.1 million and \$1.3 million, respectively, of revenue from all of our NIH grants.

Changes in Accounts receivable and Accounts payable for the three months ended March 31, 2008 and 2007 resulted from the timing of receipts from the NIH and payments made to trade vendors in the normal course of business.

Other than amounts to be received from Wyeth and from currently approved grants and contracts, we have no committed external sources of capital. Other than revenues from RELISTOR, we expect no significant product revenues for a number of years as it will take at least that much time, if ever, to bring our products to the commercial marketing stage.

Investing Activities. We purchase and sell marketable securities in order to provide funding for our operations and to achieve appreciation of our unused cash in a low risk environment. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at March 31, 2008, we continue to hold approximately \$7.7 million of auction rate securities, in respect of which we have received all scheduled interest payments, which, in the event of auction failure, are reset according to the contractual terms in the governing instrument. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid or a buyer outside the auction process emerges.

We continue to monitor the market for auction rate securities and consider its effect (if any) on the fair market value of our investments. If market conditions do not recover, we may be required to record additional impairment charges in 2008, which may affect our financial condition, cash flows and earnings. We believe that the failed auctions experienced to date are not a result of the deterioration of the underlying credit quality of these securities, although valuation of them is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. We do not believe the carrying values of these auction rate securities are permanently impaired and therefore expect the positions will eventually be liquidated without significant loss.

Our marketable securities are purchased and, in the case of auction rate securities, sold by third-party brokers in accordance with our investment policy guidelines. Our brokerage account requires that all marketable securities, other than auction rate securities, be held to maturity unless authorization is obtained from us to sell earlier. In fact, we have a history of holding all marketable securities, other than auction rate securities, to maturity. We, therefore, consider that we have the intent and ability to hold any securities with unrealized losses until a recovery of fair value, which may be maturity and we do not consider these marketable securities to be other-than-temporarily impaired at March 31, 2008.

Financing Activities. During the three months ended March 31, 2008 and 2007, we received cash of \$1.5 million and \$2.8 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants and from the sale of our common stock under our Employee Stock Purchase Plans. The amount of cash we receive from these sources fluctuates commensurate with the headcount levels and changes in the price of our common stock on the grant date for options exercised, and on the sale date for shares sold under our Employee Stock Purchase Plans.

On April 24, 2008 RELISTOR subcutaneous injection was approved by the FDA for sale in the United States for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Unless we obtain regulatory approval from the FDA for at least one of our other product candidates and/or enter into additional agreements with corporate collaborators with respect to the development of our technologies, we may be required to fund our operations for periods in the future by seeking additional financing through future offerings of equity or debt securities or funding from additional grants and government contracts. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize the future success of our business.

Table of Contents

Uses of Cash

Operating Activities. The majority of our cash has been used to advance our research and development programs. We currently have major research and development programs investigating gastroenterology, virology and oncology, and are conducting several smaller research projects in the areas of virology and oncology. Our total expenses for research and development from inception through March 31, 2008 have been approximately \$417.4 million. For various reasons, many of which are outside of our control, including the early stage of certain of our programs, the timing and results of our clinical trials and our dependence in certain instances on third parties, we cannot estimate the total remaining costs to be incurred and timing to complete our research and development programs. Under our Collaboration Agreement with Wyeth, however, we are able to estimate that those remaining costs for the subcutaneous and intravenous formulations of RELISTOR, based upon the development plan and budget approved by us and Wyeth, which defines the totality of our obligations, are \$44.2 million over the period from April 1, 2008 to December 31, 2009.

For the three months ended March 31, 2008 and 2007, research and development costs incurred, by project, were as follows:

| | Fo | For the Three Months | | | | |
|----------------|-----------|----------------------|----|------|--|--|
| | | Ended March 31, | | | | |
| | 2008 2007 | | | | | |
| | | (in millions) | | | | |
| RELISTOR | \$ | 9.3 | \$ | 10.2 | | |
| HIV | | 9.7 | | 6.4 | | |
| Cancer | | 2.5 | | 4.8 | | |
| Other programs | | 2.5 | | 1.8 | | |
| Total | \$ | 24.0 | \$ | 23.2 | | |

Although we expect that our spending on RELISTOR during the reminder of 2008 will be similar to that in 2007, our cash outlays in accordance with the agreed upon development plan will be reimbursed by Wyeth. We also expect that spending on our PRO 140, PSMA and HCV programs will increase during the reminder of 2008 and beyond. Consequently, we may require additional funding to continue our research and product development programs, to conduct pre-clinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, for the cost of product in-licensing and for any possible acquisitions. Manufacturing and commercialization expenses for RELISTOR will be funded by Wyeth. However, if we exercise our option to co-promote RELISTOR products in the U.S., which must be approved by Wyeth, we will be required to establish and fund a sales force, which we currently do not have. If we commercialize any other product candidate other than with a corporate collaborator, we would also require additional funding to establish manufacturing and marketing capabilities.

Our purchase of rights from our methylnaltrexone licensors in December 2005 has extinguished our cash payments that would have been due to those licensors in the future upon the achievement of certain events, including sales of RELISTOR products. We continue, however, to be responsible to make payments (including royalties) to the University of Chicago upon the occurrence of certain events.

We are continuing to conduct the PSMA research and development projects on our own subsequent to our acquisition of PSMA LLC and are required to fund the entire amount of such efforts; thus, increasing our cash expenditures. We are funding PSMA-related research and development efforts from our internally-generated cash flows. We are also continuing to receive funding from the NIH for a portion of our PSMA-related research and development costs.

Investing Activities. During the three months ended March 31, 2008 and 2007, we have spent \$0.8 million and \$1.1 million, respectively, on capital expenditures. Those expenditures have been related to the expansion of our office, laboratory and manufacturing facilities and the purchase of more laboratory equipment for our ongoing and future research and development projects, including the purchase of a second 150-liter bioreactor in February 2007 for the manufacture of research and clinical products.

On April 24, 2008, the Company announced that its Board of Directors had approved a share repurchase program to acquire up to \$15 million of its outstanding common shares, funding for which will come from the \$15 million milestone payment it will receive from Wyeth for receiving U.S. marketing approval for RELISTOR. Purchases under the program will be made at the Company's discretion subject to market conditions in the open-market or otherwise, and will be made in accordance with the regulations of the U.S. Securities and Exchange Commission, including Rule 10b-18. The Company has made no commitment to purchase any shares and purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired.

Table of Contents

Contractual Obligations

Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of March 31, 2008 for future payments under these agreements:

| | , | Γotal | 2 | 009 | • | ments due 010-2011 (in m | • | 012-2013 | The | reafter |
|---------------------------|----|-------|----|-----|----|--------------------------------|----|----------|-----|---------|
| Operating leases | \$ | 7.3 | \$ | 3.1 | \$ | 2.9 | \$ | 0.9 | \$ | 0.4 |
| License and collaboration | | | | | | | | | | |
| agreements (1) | | 98.0 | | 1.9 | | 5.9 | | 12.1 | | 78.1 |
| Total | \$ | 105.3 | \$ | 5.0 | \$ | 8.8 | \$ | 13.0 | \$ | 78.5 |

(1) Assumes attainment of milestones covered under each agreement, including those by PSMA LLC. The timing of the achievement of the related milestones is highly uncertain, and accordingly the actual timing of payments, if any, is likely to vary, perhaps significantly, relative to the timing contemplated by this table.

For each of our programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of the uncertainties associated with research and development of these programs, the duration and completion costs of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements could significantly increase our capital requirements and adversely impact our liquidity.

Our cash requirements may vary materially from those now planned because of results of research and development and product testing, changes in existing relationships or new relationships with, licensees, licensors or other collaborators, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory approval process, manufacturing and marketing and other costs associated with the commercialization of products following receipt of regulatory approvals and other factors.

The above discussion contains forward-looking statements based on our current operating plan and the assumptions on which it relies. There could be deviations from that plan that would consume our assets earlier than planned.

Off-Balance Sheet Arrangements and Guarantees

We have no off-balance sheet arrangements and do not guarantee the obligations of any other unconsolidated entity.

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America. Our significant accounting policies are disclosed in Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2007. The selection and application of these accounting principles and methods requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as certain financial statement disclosures. On an ongoing basis, we evaluate our estimates. We base our estimates on historical experience and on various other assumptions that are

believed to be reasonable under the circumstances. The results of our evaluation form the basis for making judgments about the carrying values of assets and liabilities that are not otherwise readily apparent. While we believe that the estimates and assumptions we use in preparing the financial statements are appropriate, these estimates and assumptions are subject to a number of factors and uncertainties regarding their ultimate outcome and, therefore, actual results could differ from these estimates.

We have identified our critical accounting policies and estimates below. These are policies and estimates that we believe are the most important in portraying our financial condition and results of operations, and that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We have discussed the development, selection and disclosure of these critical accounting policies and estimates with the Audit Committee of our Board of Directors.

Table of Contents

Revenue Recognition

We recognize revenue from all sources based on the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 104 ("SAB 104") "Revenue Recognition," Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21") "Accounting for Revenue Arrangements with Multiple Deliverables" and EITF Issue No. 99-19 ("EITF 99-19") "Reporting Revenue Gross as a Principal Versus Net as an Agent." Our license and co-development agreement with Wyeth includes a non-refundable upfront license fee, reimbursement of development costs, research and development payments based upon our achievement of clinical development milestones, contingent payments based upon the achievement by Wyeth of defined events and royalties on product sales. We began recognizing research revenue from Wyeth on January 1, 2006. During the three months ended March 31, 2008 and 2007, we also recognized revenue from government research grants and contracts, which are used to subsidize a portion of certain of our research projects ("Projects"), exclusively from the NIH. We also recognized revenue from the sale of research reagents during those periods.

Non-refundable upfront license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and steering or other committee services, can be separated in accordance with EITF 00-21. We would recognize upfront license payments as revenue upon delivery of the license only if the license had standalone value and the fair value of the undelivered performance obligations, typically including research or steering or other committee services, could be determined. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations could not be determined, the upfront license payments would be recognized as revenue over the estimated period of when our performance obligations are performed.

We must determine the period over which our performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents will typically be used as the measure of performance. Under the proportionate performance method, revenue related to upfront license payments is recognized in any period as the percent of actual effort expended in that period relative to total effort for all of our performance obligations under the arrangement. We are recognizing revenue related to the upfront license payment we received from Wyeth using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Collaboration Agreement with Wyeth based upon the most current budget approved by both Wyeth and us. Such performance obligations are provided by us on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. Since we have no obligation to develop the subcutaneous and intravenous formulations of RELISTOR outside the U.S. or the oral formulation at all and have no significant commercialization obligations for any product, recognition of revenue for the upfront payment is not required during those periods, if they extend beyond the period of our development obligations.

During the course of a collaboration agreement, e.g., the Collaboration Agreement with Wyeth, that involves a development plan and budget, the amount of the upfront license payment that is recognized as revenue in any period

will increase or decrease as the percentage of actual effort increases or decreases, as described above. When a new budget is approved, generally annually, the remaining unrecognized amount of the upfront license fee will be recognized prospectively, using the methodology described above and applying any changes in the total estimated effort or period of development that is specified in the revised approved budget. The amounts of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 were based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amounts of revenue recognized in those periods. During the third quarter of 2007, however, the estimate of our total remaining effort to complete our development obligations was increased significantly based upon a revised development budget approved by both us and Wyeth. As a result, the period over which our obligations will extend, and over which the upfront payment will be amortized, was extended from the end of 2008 to the end of 2009. Consequently, the amount of revenue recognized from the upfront payment in the first quarter of 2008 declined relative to that in the comparable period of 2007. Due to the significant judgments involved in determining the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement, further changes in any of those judgments are reasonably likely to occur in the future which could have a material impact on our revenue recognition. If a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an upfront payment at the time of the termination.

Table of Contents

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement and the performance obligations are provided on a best-efforts basis, then the total upfront license payments would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations.

If we are involved in a steering or other committee as part of a multiple element arrangement, we assess whether our involvement constitutes a performance obligation or a right to participate. For those committees that are deemed obligations, we will evaluate our participation along with other obligations in the arrangement and will attribute revenue to our participation through the period of our committee responsibilities. In relation to the Collaboration Agreement with Wyeth, we have assessed the nature of our involvement with the Joint Steering, Joint Development and Joint Commercialization Committees. Our involvement in the first two such Committees is one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. We have combined the committee obligations with the other development obligations and are accounting for these obligations during the development phase as a single unit of accounting. After the development period, however, we have assessed the nature of our involvement with the three Committees to be a right, rather than an obligation. Our assessment is based upon the fact we negotiated to be on these Committees as an accommodation for our granting of the license for RELISTOR to Wyeth. Further, Wyeth has been granted by us an exclusive license (even as to us) to the technology and know-how regarding RELISTOR and has been assigned the agreements for the manufacture of RELISTOR by third parties. Following regulatory approval of the subcutaneous and intravenous formulations of RELISTOR, Wyeth will continue to develop the oral formulation and to commercialize all formulations, for which it is capable and responsible. During those periods, the activities of these Committees will be focused on Wyeth's development and commercialization obligations.

Collaborations may also contain substantive milestone payments. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (i) the milestone payment is non-refundable; (ii) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved in achieving the milestone, (iv) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (v) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment (the "Substantive Milestone Method"). During October 2006 and May 2007, we earned \$5.0 million and \$9.0 million, respectively, upon achievement of non-refundable milestones anticipated in the Collaboration Agreement with Wyeth; the first in connection with the commencement of a phase 3 clinical trial of the intravenous formulation of RELISTOR and the second in connection with the submission and acceptance for review of an NDA for a subcutaneous formulation of RELISTOR with the FDA and a comparable submission in the European Union. We considered those milestones to be substantive based on the significant degree of risk at the inception of the Collaboration Agreement related to the conduct and successful completion of clinical trials and, therefore, of not achieving the milestones; the amount of the payment received relative to the significant costs incurred since inception of the Collaboration Agreement and amount of effort expended to achieve the milestones; and the passage of ten and seventeen months, respectively, from inception of the Collaboration Agreement to the achievement of those milestones. Therefore, we recognized the milestone payments as revenue in the respective periods in which the milestones were earned.

Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone and, therefore, the resulting payment would be considered part of the consideration and be recognized as revenue as such performance obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

We will recognize revenue for payments that are contingent upon performance solely by our collaborator immediately upon the achievement of the defined event if we have no related performance obligations.

Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Royalty revenue is recognized upon the sale of related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement. If royalties are received when we have remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and, therefore, would be recognized as such performance obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

Table of Contents

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term deferred revenue. The estimate of the classification of deferred revenue as short-term or long-term is based upon management's current operating budget for the Wyeth collaboration agreement for our total effort required to complete our performance obligations under that arrangement. That estimate may change in the future and such changes to estimates would be accounted for prospectively and would result in a change in the amount of revenue recognized in future periods.

NIH grant and contract revenue is recognized as efforts are expended and as related subsidized Project costs are incurred. We perform work under the NIH grants and contract on a best-effort basis. The NIH reimburses us for costs associated with Projects in the fields of virology and cancer, including pre-clinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus, as requested by the NIH. Substantive at-risk milestone payments are uncommon in these arrangements, but would be recognized as revenue on the same basis as the Substantive Milestone Method.

Share-Based Payment Arrangements

Our share-based compensation to employees includes non-qualified stock options, restricted stock (nonvested shares) and shares issued under our Employee Stock Purchase Plans (the "Purchase Plans"), which are compensatory under Statement of Financial Accounting Standards No. 123 (revised 2004) ("SFAS No. 123(R)") "Share-Based Payment." We account for share-based compensation to non-employees, including non-qualified stock options and restricted stock (nonvested shares), in accordance with Emerging Issues Task Force Issue No. 96-18 "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Connection with Selling, Goods or Services."

We adopted SFAS No. 123(R) using the modified prospective application, under which compensation cost for all share-based awards that were unvested as of January 1, 2006, the adoption date, and those newly granted or modified after the adoption date will be recognized in our financial statements over the related requisite service periods; usually the vesting periods for awards with a service condition. Compensation cost is based on the grant-date fair value of awards that are expected to vest. We apply a forfeiture rate to the number of unvested awards in each reporting period in order to estimate the number of awards that are expected to vest. Estimated forfeiture rates are based upon historical data on vesting behavior of employees. We adjust the total amount of compensation cost recognized for each award, in the period in which each award vests, to reflect the actual forfeitures related to that award. Changes in our estimated forfeiture rate will result in changes in the rate at which compensation cost for an award is recognized over its vesting period. We have made an accounting policy decision to use the straight-line method of attribution of compensation expense, under which the grant date fair value of share-based awards will be recognized on a straight-line basis over the total requisite service period for the total award.

Under SFAS No. 123(R), the fair value of each non-qualified stock option award is estimated on the date of grant using the Black-Scholes option pricing model, which requires input assumptions of stock price on the date of grant, exercise price, volatility, expected term, dividend rate and risk-free interest rate.

We use the closing price of our common stock on the date of grant, as quoted on The NASDAQ Stock Market

• LLC, as the exercise price.

Historical volatilities are based upon daily quoted market prices of our common stock on The NASDAQ

• Stock Market LLC over a period equal to the expected term of the related equity instruments. We rely only on historical volatility since it provides the most reliable indication of future volatility. Future volatility is expected to be consistent with historical; historical volatility is calculated using a simple average calculation; historical data is available for the length of the option's expected term and a sufficient number of price

observations are used consistently. Since our stock options are not traded on a public market, we do not use implied volatility. For the three months ended March 31, 2008 and 2007, the volatility of our common stock has been high, 66% - 90% and 55% - 89%, respectively, which is common for entities in the biotechnology industry that do not have commercial products. A higher volatility input to the Black-Scholes model increases the resulting compensation expense.

The expected term of options granted represents the period of time that options granted are expected to be outstanding. For the three months ended March 31, 2008 and 2007, our expected term was calculated based upon historical data related to exercise and post-termination cancellation activity for each of two groups of recipients of stock options: employees, and officers and directors. Accordingly, for grants made to each of the groups mentioned above, we are using expected terms of 5.33 and 8 years and 5.25 and 7.5 years, respectively. Expected term for options granted to non-employee consultants was ten years, which is the contractual term of those options. A shorter expected term would result in a lower compensation expense.

Table of Contents

• We have never paid dividends and do not expect to pay dividends in the future. Therefore, our dividend rate is zero.

The risk-free rate for periods within the expected term of the options is based on the U.S. Treasury yield curve in • effect at the time of grant.

A portion of the options granted to our Chief Executive Officer on July 1, 2002, 2003, 2004 and 2005, on July 3, 2006 and on July 2, 2007 cliff vests after nine years and eleven months from the respective grant date. Vesting of a defined portion of each award will occur earlier if a defined performance condition is achieved; more than one condition may be achieved in any period. In accordance with SFAS No. 123(R), at the end of each reporting period, we will estimate the probability of achievement of each performance condition and will use those probabilities to determine the requisite service period of each award. The requisite service period for the award is the shortest of the explicit or implied service periods. In the case of the executive's options, the explicit service period is nine years and eleven months from the respective grant dates. The implied service periods related to the performance conditions are the estimated times for each performance condition to be achieved. Thus, compensation expense will be recognized over the shortest estimated time for the achievement of performance conditions for that award (assuming that the performance conditions will be achieved before the cliff vesting occurs). Changes in the estimate of probability of achievement of any performance condition will be reflected in compensation expense of the period of change and future periods affected by the change.

The fair value of shares purchased under the Purchase Plans is estimated on the date of grant in accordance with FASB Technical Bulletin No. 97-1 "Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option." The same option valuation model is used for the Purchase Plans as for non-qualified stock options, except that the expected term for the Purchase Plans is six months and the historical volatility is calculated over the six month expected term.

In applying the treasury stock method for the calculation of diluted earnings per share ("EPS"), amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted earnings per share calculation unless they are anti-dilutive. We incurred a net loss for the three months ended March 31, 2008 and 2007, and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for those periods. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculations, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

For the three months ended March 31, 2008, no tax benefit was recognized related to total compensation cost for share-based payment arrangements recognized in operations because we had a net loss for the period and the related deferred tax assets were fully offset by a valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the three months ended March 31, 2008.

Research and Development Expenses Including Clinical Trial Expenses

Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our contracts with various clinical investigators and clinical research organizations in connection with conducting clinical trials for our product candidates. Such costs are expensed based on the expected total number of patients in the trial, the rate at which the patients enter the trial and the period over which the clinical investigators and clinical

research organizations are expected to provide services. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates. Our collaboration agreement with Wyeth regarding RELISTOR in which Wyeth has assumed all of the financial responsibility for further development will mitigate those costs. In addition to clinical trial expenses, we estimate the amounts of other research and development expenses, for which invoices have not been received at the end of a period, based upon communication with third parties that have provided services or goods during the period.

On January 1, 2008, we adopted Emerging Issues Task Force Issue 07-3 ("EITF 07-3") "Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities." Prior to January 1, 2008, under FASB Statement No. 2, "Accounting for Research and Development Costs," non-refundable advance payments for future research and development activities for materials, equipment, facilities and purchased intangible assets that had no alternative future use were expensed as incurred. Beginning in the quarter ended March 31, 2008, we have been capitalizing such non-refundable advance payments and expensing them as the goods are delivered or the related services are performed. EITF 07-3 applies to new contracts entered into after the effective date of January 1, 2008. The impact of applying EITF 07-3 did not have a material impact on the financial position or results of operations for the quarter ended March 31, 2008.

Table of Contents

Fair Value Measurements

Our available-for-sale investment portfolio consists of marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, and is recorded at fair value in the accompanying Condensed Consolidated Balance Sheets in accordance with Financial Accounting Standards Board ("FASB") Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities." The change in the fair value of these investments is recorded as a component of other comprehensive income.

We adopted FASB Statement No. 159 ("FAS 159") "The Fair Value Option of Financial Assets and Financial Liabilities" effective January 1, 2008, which provides companies with an option to report certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. FAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The objective of FAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. We have elected not to apply the fair value option to any of its assets or liabilities.

We also adopted FASB Statement No. 157 ("FAS 157") "Fair Value Measurements" effective January 1, 2008 for financial assets and financial liabilities. FAS 157 defines fair value as the price that would be received to sell an asset or would be paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date, and establishes a framework to make the measurement of fair value more consistent and comparable. In accordance with Financial Accounting Standards Board Staff Position (FSP) 157-2, "Effective Date of FASB Statement No. 157," we will defer the adoption of FAS 157 for our nonfinancial assets and nonfinancial liabilities, until January 1, 2009. We are currently evaluating the impact of FAS 157 for nonfinancial assets and nonfinancial liabilities, and the adoption of this statement is not expected to have a material effect on our financial position or results of operations. The partial adoption of FAS 157 did not have a material impact on our fair value measurements.

FAS 157 established a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed based on market data obtained from sources independent of the reporting entity ("observable inputs") and the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances ("unobservable inputs"). The hierarchy level assigned to each security in our available-for-sale portfolio is based on our assessment of the transparency and reliability of the inputs used in the valuation of such instrument at the measurement date. The three hierarchy levels are defined as follows:

Level 1 - Valuations based on unadjusted quoted market prices in active markets for identical securities.

•

Level 2 - Valuations based on observable inputs (other than Level 1 prices), such as quoted prices for similar assets
at the measurement date; quoted prices in markets that are not active; or other inputs that are observable, either directly or indirectly.

Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement,
• and involve management judgment.

Impact of Recently Issued Accounting Standards

In March 2008, the Financial Accounting Standards Board ("FASB") issued SFAS No. 161 ("FAS 161") "Disclosures about Derivative Instruments and Hedging Activities – an amendment to FASB Statement No. 133," which is intended

to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (i) how and why an entity uses derivative instruments; (ii) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations; and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. We do not expect the effect of the adoption of FAS 161 to have a material effect on our financial position or results of operations.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary investment objective is to preserve principal while maximizing yield without significantly increasing our risk. Our investments consist of taxable auction rate securities, corporate notes and issues of government sponsored entities. Our investments totaled \$149.8 million at March 31, 2008. Approximately \$120.6 million of these investments had fixed interest rates, and \$29.2 million had interest rates that were variable.

Due to the conservative nature of our short-term fixed interest rate investments, we do not believe that we have a material exposure to interest rate risk. Our fixed-interest-rate long-term investments are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair values of these investments due to differences between the market interest rate and the rate at the date of purchase of the investment. A 100 basis point increase in the March 31, 2008 market interest rates would result in a decrease of approximately \$0.096 million in the market values of these investments.

Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at March 31, 2008, we continue to hold approximately \$7.7 million of auction rate securities, in respect of which we have received all scheduled interest payments, which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid or a buyer outside the auction process emerges.

We continue to monitor the market for auction rate securities and consider its effect (if any) on the fair market value of our investments. If market conditions do not recover, we may be required to record additional impairment charges in 2008, which may affect our financial condition, cash flows and earnings. We believe that the failed auctions experienced to date are not a result of the deterioration of the underlying credit quality of these securities, although valuation of them is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. We do not believe the carrying values of these auction rate securities are permanently impaired and therefore expect the positions will eventually be liquidated without significant loss.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We also established a Disclosure Committee that consists of certain

members of our senior management.

The Disclosure Committee, under the supervision and with the participation of our senior management, including our Chief Executive Officer and Principal Financial and Accounting Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective.

There have been no changes in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II — OTHER INFORMATION

Item 1A. Risk Factors

Our business and operations entail a variety of serious risks and uncertainties, including those described in Item 1A of our Form 10-K for the year ended December 31, 2007. In addition, the following risk factors have changed during the quarter ended March 31, 2008:

Our product development programs are inherently risky.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies.

We have received marketing approvals in the U.S. and other countries for the sale of RELISTOR subcutaneous injection for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. We continue to develop RELISTOR subcutaneous injection for other indications, and, together with Wyeth, are also developing intravenous and oral formulations of RELISTOR. We will have to complete successfully additional clinical trials and obtain regulatory approvals for these additional formulations and indications. Our other research and development programs, including those related to PSMA, involve novel approaches to human therapeutics. For example, our principal HIV product candidate, the monoclonal antibody PRO 140, is designed to block viral entry. To our knowledge, there are two approved drugs designed to treat HIV infection by blocking viral entry (Trimeris' FUZEONTM and Pfizer's SELZENTRYTM) that have been approved for marketing in the U.S., but neither are monoclonal antibodies. There is little precedent for the successful commercialization of products based on our technologies. There are a number of technological challenges that we must overcome to complete most of our development efforts. We may not be able successfully to develop further any of our products.

We have granted to Wyeth the exclusive rights to develop and commercialize RELISTOR, our lead product candidate, and our resulting dependence upon Wyeth exposes us to significant risks.

In December 2005, we entered into a license and co-development agreement with Wyeth. Under this agreement, we granted to Wyeth the exclusive worldwide right to develop and commercialize RELISTOR. As a result, we are dependent upon Wyeth to perform and fund development, including clinical testing, to make certain regulatory filings and to manufacture and market products containing RELISTOR. Our collaboration with Wyeth may not be scientifically, clinically or commercially successful.

Revenues from the sale of RELISTOR will depend almost entirely upon the efforts of Wyeth. Wyeth has significant discretion in determining the efforts and resources it applies to sales of the RELISTOR products and may not be effective in marketing such products. In addition, Wyeth is a large, diversified pharmaceutical company with global operations and its own corporate objectives, which may not be consistent with our best interests. For example, Wyeth may change its strategic focus or pursue alternative technologies in a manner that results in reduced revenues to us. Our continued receipt of milestone and royalty payments from Wyeth will be dependent on Wyeth's commercialization efforts. As of March 31, 2008, we have received \$14.0 million in milestone payments from Wyeth, and we have subsequently earned an additional \$15.0 million milestone payment for the FDA approval of subcutaneous RELISTOR. We may not receive any further milestone or royalty payments from Wyeth.

The Collaboration Agreement extends, unless terminated earlier, on a country-by-country and product-by-product basis, until the last-to-expire royalty period, as defined, for any product. Progenics may terminate the Collaboration Agreement at any time upon 90 days of written notice to Wyeth (30 days in the case of breach of a payment obligation) upon material breach that is not cured. Wyeth may, with or without cause, following the second

anniversary of the first commercial sale, as defined, of the first commercial product in the U.S., terminate the Collaboration Agreement by providing Progenics with at least 360 days prior written notice of such termination. Wyeth may also terminate the agreement (i) upon 30 days written notice following one or more serious safety or efficacy issues that arise, as defined, and (ii) at any time, upon 90 days written notice of a material breach that is not cured by Progenics. Upon termination of the Collaboration Agreement, the ownership of the license we granted to Wyeth will depend on the party that initiates the termination and the reason for the termination.

If our relationship with Wyeth were to terminate, we would have to either enter into a license and co-development agreement with another party or continue to develop and commercialize RELISTOR ourselves. We may not be able to enter into such an agreement with another suitable company on acceptable terms or at all. To continue to develop and commercialize RELISTOR on our own, we would have to develop a sales and marketing organization and a distribution infrastructure, neither of which we currently have. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability.

Table of Contents

A termination of our relationship with Wyeth could seriously compromise the RELISTOR program and possibly our other product candidates. For example, we could experience significant delays and would have to assume full funding and other responsibility for further development and commercialization.

Any of these outcomes would result in delays in our ability to distribute RELISTOR and would increase our expenses, which would have a material adverse effect on our business, results of operations and financial condition.

Our collaboration with Wyeth is multi-faceted and involves a complex sharing of control over decisions, responsibilities, costs and benefits. There are numerous potential sources of disagreement between us and Wyeth, including with respect to product development, marketing strategies, manufacturing and supply issues and rights relating to intellectual property. Wyeth has significantly greater financial and managerial resources than we do, which it could draw upon in the event of a dispute. A disagreement between Wyeth and us could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as to extensive financial and operational consequences to us, and have a material adverse effect on our business, results of operations and financial condition.

If testing does not yield successful results, our products will not be approved.

We are required to obtain regulatory approval before our product candidates can be marketed. To obtain marketing approval from regulatory authorities, we or our collaborators must demonstrate a product's safety and efficacy through extensive pre-clinical and clinical testing. Numerous adverse events may arise during, or as a result of, the testing process, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials:
- potential products may not have the desired efficacy or may have undesirable side effects or other characteristics that preclude marketing approval or

limit their commercial use if approved;

- after reviewing test results, we or our collaborators may abandon projects which we previously believed to be promising; and
- we, our collaborators or regulators may suspend or terminate clinical trials if we or they believe that the
 participating subjects are being exposed to unacceptable
 health risks.

Clinical testing is very expensive and can take many years. Results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials. In addition, many of our investigational or experimental drugs, such as PRO 140 and the PSMA product candidates, are at an early stage of development. The successful commercialization of early stage product candidates will require significant further research, development, testing and approvals by regulators and additional investment. Our products in the research or pre-clinical development stage may not yield results that would permit or justify clinical testing. Our failure to demonstrate adequately the safety and efficacy of a product under development would delay or prevent marketing approval of the product, which could adversely affect our operating results and credibility.

A setback in our clinical development programs could adversely affect us.

We and Wyeth continue to conduct clinical trials of RELISTOR. If the results of any of these ongoing trials or of other future trials of RELISTOR are not satisfactory, or if we encounter problems enrolling subjects, or if clinical trial

supply issues or other difficulties arise, our entire RELISTOR development program could be adversely affected, resulting in delays in commencing or completing clinical trials or in making regulatory filing for further marketing approval. The need to conduct additional clinical trials or significant revisions to our clinical development plan would lead to delays in filing for additional regulatory approvals necessary to market RELISTOR for additional indications in other formulations and settings. If the clinical trials indicate a serious problem with the safety or efficacy of a RELISTOR product, then Wyeth has the right under our license and co-development agreement to terminate the agreement or to stop the development or commercialization of the affected products. Since RELISTOR is our most clinically advanced product, any setback of these types would have a material adverse effect on our stock price and business.

We are conducting a clinical trial of PRO 140 and are planning trials of PSMA ADC and prostate cancer vaccine candidates. If the results of our future clinical studies of PRO 140 or the pre-clinical and clinical studies involving the PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved.

Table of Contents

We have a history of operating losses, and we may never be profitable.

We have incurred substantial losses since our inception. As of March 31, 2008, we had an accumulated deficit of \$269.5 million. We have derived no significant revenues from product sales or royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur additional operating losses in the future, which could increase significantly as we expand our clinical trial programs and other product development efforts.

Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval to market our products and then commercializing, either alone or with others, our products. We may not be able to develop and commercialize products. Our operations may not be profitable even if any of our products under development are commercialized.

We are likely to need additional financing, but our access to capital funding is uncertain.

As of March 31, 2008, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$155.0 million. During the three months ended March 31, 2008, we had a net loss of \$15.5 million and cash used in operating activities was \$16.4 million. Our accumulated deficit is expected to increase in the future.

Under our agreement with Wyeth, Wyeth is responsible for all future development and commercialization costs relating to RELISTOR starting January 1, 2006. As a result, although our spending on RELISTOR has been significant during the first quarter of 2008 and 2007 and is expected to continue at a similar level in the future, our net expenses for RELISTOR have been and will continue to be reimbursed by Wyeth.

With regard to our other product candidates, we expect that we will continue to incur significant expenditures for their development, and we do not have committed external sources of funding for most of these projects. These expenditures will be funded from our cash on hand, or we may seek additional external funding for these expenditures, most likely through collaborative agreements, or other license or sale transactions, with one or more pharmaceutical companies, through the issuance and sale of securities or through additional government grants or contracts. We cannot predict with any certainty when we will need additional funds or how much we will need or if additional funds will be available to us. Our need for future funding will depend on numerous factors, many of which are outside our control.

Our access to capital funding is always uncertain. Despite previous experience, we may not be able at the necessary time to obtain additional funding on acceptable terms, or at all. Our inability to raise additional capital on terms reasonably acceptable to us may jeopardize the future success of our business.

If we raise funds by issuing and selling securities, it may be on terms that are not favorable to our existing stockholders. If we raise additional funds by selling equity securities, our current stockholders will be diluted, and new investors could have rights superior to our existing stockholders. If we raise funds by selling debt securities, we could be subject to restrictive covenants and significant repayment obligations.

We believe that existing balances of cash, cash equivalents and marketable securities and cash generated from operations are sufficient to finance our current operations and working capital requirements on both a short-term and long-term basis. We cannot, however, predict the amount or timing of our need for additional funds under various circumstances, which could include new product development projects, other opportunities or other factors that may require us to raise additional funds in the future. Purchases of our common shares pursuant to our recently announced \$15 million share repurchase program would reduce the amount of cash on hand available for unforeseen needs.

Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at March 31, 2008, we continue to hold approximately \$7.7 million of auction rate securities, in respect of which we have received all scheduled interest payments, which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid or a buyer outside the auction process emerges.

Table of Contents

We continue to monitor the market for auction rate securities and consider its effect (if any) on the fair market value of our investments. If market conditions do not recover, we may be required to record additional impairment charges in 2008, which may affect our financial condition, cash flows and earnings. We believe that the failed auctions experienced to date are not a result of the deterioration of the underlying credit quality of these securities, although valuation of them is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. We do not believe the carrying values of these auction rate securities are permanently impaired and therefore expect the positions will eventually be liquidated without significant loss.

Our clinical trials could take longer than we expect.

Although for planning purposes we forecast the commencement and completion of clinical trials, and have included many of those forecasts in reports filed with the SEC and in other public disclosures, the actual timing of these events can vary dramatically. For example, we have experienced delays in our RELISTOR clinical development program in the past as a result of slower than anticipated enrollment. These delays may recur. Delays can be caused by, among other things:

- deaths or other adverse medical events involving subjects in our clinical trials;
 - regulatory or patent issues;
 - interim or final results of ongoing clinical trials;
 - failure to enroll clinical sites as expected;
- competition for enrollment from clinical trials conducted by others in similar indications;
 - scheduling conflicts with participating clinicians and clinical institutions; and
 - manufacturing problems.

In addition, we may need to delay or suspend our clinical trials if we are unable to obtain additional funding when needed. Clinical trials involving our product candidates may not commence or be completed as forecasted.

We have limited experience in conducting clinical trials, and we rely on others to conduct, supervise or monitor some or all aspects of some of our clinical trials. In addition, certain clinical trials for our product candidates may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. Under our agreement with Wyeth relating to RELISTOR, Wyeth has the responsibility to conduct some of the clinical trials for that product, including all trials outside of the United States. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

As a result of these and other factors, our clinical trials may not commence or be completed as we expect or may not be conducted successfully, in which event investors' confidence in our ability to develop products may be impaired and our stock price may decline.

Our product candidates may not obtain regulatory approvals needed for marketing.

None of our product candidates other than RELISTOR has been approved by applicable regulatory authorities for marketing. The process of obtaining FDA and foreign regulatory approvals often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We have had only limited experience in filing and pursuing applications and other submissions necessary to gain marketing approvals. Products under development may never obtain the marketing approval from the FDA or any other regulatory authority necessary for commercialization.

Even if our products receive regulatory approval:

they might not obtain labeling claims necessary to make the product commercially viable (in general, labeling • claims define the medical conditions for which a drug product may be marketed, and are therefore very important to the commercial success of a product);

Table of Contents

approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are • relatively less financially advantageous to us than approval of greater or different scope;

we or our collaborators might be required to undertake post-marketing trials to verify the product's efficacy or • safety;

we, our collaborators or others might identify side effects after the product is on the market, or we or our collaborators might experience manufacturing problems, either of which could result in subsequent withdrawal of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product or the need for additional marketing applications; and

we and our collaborators will be subject to ongoing FDA obligations and continuous regulatory review.

If our products fail to receive marketing approval or lose previously received approvals, our financial results would be adversely affected.

One or more competitors developing an opioid antagonist may reach the market ahead of us and adversely affect the market potential for RELISTOR.

We are aware that Adolor Corporation, in collaboration with Glaxo Group Limited, or Glaxo, a subsidiary of GlaxoSmithKline plc, is developing EnteregTM (alvimopan), an opioid antagonist, for postoperative ileus, which has completed phase 3 clinical trials, and for opioid-induced bowel dysfunction, which has been the subject of phase 3 clinical trials. Adolor has received an approvable letter from the FDA for Entereg regarding the treatment of post-operative ileus. If Entereg reaches the market before RELISTOR in one or more formulations for particular indications or settings, it could achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of Glaxo may impair our ability to penetrate the market.

Under the terms of our collaboration with Wyeth with respect to RELISTOR, Wyeth is developing the oral formulation of RELISTOR worldwide. We are leading the U.S. development of the subcutaneous and intravenous formulations of RELISTOR, while Wyeth is leading development of these parenteral products outside the U.S. Decisions regarding the timelines for development of the three RELISTOR formulations are being be made by a Joint Development Committee, and endorsed by the Joint Steering Committee, each committee formed under the terms of the license and co-development agreement, consisting of members from both Wyeth and Progenics.

We are dependent upon third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.

We rely in part on third parties to perform a variety of functions. We are party to numerous agreements which place substantial responsibility on clinical research organizations, consultants and other service providers for the development of our products. We also rely on medical and academic institutions to perform aspects of our clinical trials of product candidates. In addition, an element of our research and development strategy is to in-license technology and product candidates from academic and government institutions in order to minimize investments in early research. We entered into an agreement under which we depend on Wyeth for the commercialization and development of RELISTOR. We may not be able to maintain any of these relationships or establish new ones on beneficial terms. We may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully.

Our stock price has a history of volatility. You should consider an investment in our stock as risky and invest only if you can withstand a significant loss.

Our stock price has a history of significant volatility. Between January 1, 2006 and March 31, 2008, our stock price has ranged from \$4.33 to \$30.83 per share. Historically, our stock price has fluctuated through an even greater range. At times, our stock price has been volatile even in the absence of significant news or developments relating to us. The stock prices of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years. Factors that may have a significant impact on the market price of our common stock include:

- the results of clinical trials and pre-clinical studies involving our products or those of our competitors;
- changes in the status of any of our drug development programs, including delays in clinical trials or program terminations;

Table of Contents

- developments regarding our efforts to achieve marketing approval for our products;
- developments in our relationship with Wyeth regarding the development and commercialization of RELISTOR;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
- developments in our relationships with other collaborative partners;
- developments in patent or other proprietary rights;
- governmental regulation;
- changes in reimbursement policies or health care legislation;
- public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
- our ability to fund on-going operations;
- fluctuations in our operating results; and
- general market conditions.

Purchases of our common shares pursuant to our recently announced \$15 million share repurchase program may, depending on their timing, volume and form, may result in our stock price to be higher than it would be in the absence of such purchases. If purchases under the program are not initiated or are discontinued, our stock price may fall.

Our principal stockholders are able to exert significant influence over matters submitted to stockholders for approval.

At March 31, 2008, our directors and executive officers and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately one-fourth of our outstanding shares of common stock. At that date, our five largest stockholders, excluding our directors and executive officers and stockholders affiliated with Tudor, beneficially own or control in the aggregate approximately one-third of our outstanding shares. Our directors and executive officers and Tudor-related stockholders, should they choose to act together, could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could have the effect of delaying or preventing a change in control of us and, consequently, could adversely affect the market price of our common stock. Other significant but unrelated stockholders could also exert influence in such matters.

Item 6. Exhibits

(a) Exhibits

31.1

Certification of Paul J. Maddon, M.D., Ph.D., Chief Executive Officer of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended

31.2 Certification of Robert A. McKinney, Chief Financial Officer and Senior Vice President, Finance and Operations (Principal Financial and Accounting Officer) of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended

Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the 32 Sarbanes-Oxley Act of 2002

Table of Contents

SIGNATURES

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.

PROGENICS PHARMACEUTICALS, INC.

Date: May 9, 2008 By: /s/ Robert A. McKinney

Robert A. McKinney Chief Financial Officer

Senior Vice President, Finance & Operations and

Treasurer

(Duly authorized officer of the Registrant and Principal Financial and Accounting Officer)