

PROGENICS PHARMACEUTICALS INC

Form 10-Q

November 10, 2008

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

OR

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

For the transition period from _____ to _____

Commission file number 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

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or 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:

Large accelerated filer ☐

Accelerated filer ☒

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 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of November 5, 2008 there were 30,456,339 shares of common stock, par value \$.0013 per share, of the registrant outstanding.

PROGENICS PHARMACEUTICALS, INC.

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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)

	September 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 19,695	\$ 10,423
Marketable securities	83,946	120,000
Accounts receivable	6,832	1,995
Other current assets	2,789	3,111
Total current assets	113,262	135,529
Marketable securities	30,953	39,947
Fixed assets, at cost, net of accumulated depreciation and amortization	12,104	13,511
Restricted cash	520	552
Other assets	6	-
Total assets	\$ 156,845	\$ 189,539
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 11,416	\$ 14,765
Deferred revenue ³ / ₄ current	14,177	17,728
Other current liabilities	57	57
Total current liabilities	25,650	32,550
Deferred revenue — long term	2,833	9,131
Other liabilities	290	359
Total liabilities	28,773	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 — 30,555,655 in 2008 and 29,753,820 in 2007	40	39
Additional paid-in capital	417,543	401,500
Accumulated deficit	(284,120)	(254,046)
Accumulated other comprehensive (loss) income	(2,650)	6
Treasury stock, at cost (200,000 shares)	(2,741)	-
Total stockholders' equity	128,072	147,499
Total liabilities and stockholders' equity	\$ 156,845	\$ 189,539

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

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PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Research and development from collaborator	\$ 16,015	\$ 14,540	\$ 54,896	\$ 52,987
Royalty income	44	-	86	-
Research grants and contract	1,377	2,471	5,689	7,077
Other revenues	61	7	172	48
Total revenues	17,497	17,018	60,843	60,112
Expenses:				
Research and development	21,478	24,263	68,191	69,166
License fees – research and development	305	(16)	1,788	833
General and administrative	8,265	9,275	22,530	21,746
Royalty expense	5	-	9	-
Depreciation and amortization	1,166	845	3,427	2,144
Total expenses	31,219	34,367	95,945	93,889
Operating loss	(13,722)	(17,349)	(35,102)	(33,777)
Other income:				
Interest income	1,502	1,749	5,028	5,361
Total other income	1,502	1,749	5,028	5,361
Net loss	\$ (12,220)	\$ (15,600)	\$ (30,074)	\$ (28,416)
Net loss per share - basic and diluted	\$ (0.41)	\$ (0.58)	\$ (1.02)	\$ (1.07)
Weighted-average shares - basic and diluted	29,820	26,976	29,553	26,639

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

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PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE
LOSS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008

(amounts in thousands)
(Unaudited)

	Common Stock		Additional		Accumulated Other Comprehensive (Loss) Income		Treasury Stock		Total
	Shares	Amount	Paid-In Capital	Accumulated Deficit			Shares	Amount	
Balance at December 31, 2007	29,754	\$ 39	\$ 401,500	\$ (254,046)	\$ 6		-	\$ -	\$ 147,499
Comprehensive loss:									
Net (loss)	-	-	-	(30,074)	-		-	-	(30,074)
Net change in unrealized gain on marketable securities	-	-	-	-	(2,656)		-	-	(2,656)
Total comprehensive loss:									(32,730)
Compensation expense for vesting of share-based payment arrangements	-	-	10,899	-	-		-	-	10,899
Issuance of restricted stock, net of forfeitures	164	-	-	-	-		-	-	-
Sale of common stock under employee stock purchase plans and exercise of	638	1	5,144	-	-		-	-	5,145

stock options

Treasury shares
acquired under
repurchase
program

- - - - - (200) (2,741) (2,741)

Balance at
September 30,
2008

30,556 \$ 40 \$ 417,543 \$ (284,120) \$ (2,650) (200) \$ (2,741) \$ 128,072

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

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PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (30,074)	\$ (28,416)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,427	2,144
Amortization of discounts, net of premiums, on marketable securities	620	(354)
Vesting of share-based compensation awards	10,899	11,840
Changes in assets and liabilities:		
Increase in accounts receivable	(4,837)	(505)
Decrease in other current assets	322	626
Increase in other assets	(6)	-
(Decrease) increase in accounts payable and accrued expenses	(3,349)	3,761
Decrease in deferred revenue	(9,849)	(14,252)
(Decrease) increase in deferred lease liability	(69)	57
Increase in other liabilities	-	232
Net cash used in operating activities	(32,916)	(24,867)
Cash flows from investing activities:		
Capital expenditures	(2,020)	(4,359)
Sales/maturities of marketable securities	96,734	188,997
Purchase of marketable securities	(54,962)	(170,565)
Decrease (increase) in restricted cash	32	(5)
Net cash provided by investing activities	39,784	14,068
Cash flows from financing activities:		
Proceeds from sale of common stock in public offering	-	60,190
Expenses related to the sale of common stock in public offering	-	(3,058)
Purchase of treasury stock	(2,741)	-
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	5,145	6,107
Repurchase of restricted stock	-	(19)
Net cash provided by financing activities	2,404	63,220
Net increase in cash and cash equivalents	9,272	52,421
Cash and cash equivalents at beginning of period	10,423	11,947
Cash and cash equivalents at end of period	\$ 19,695	\$ 64,368

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

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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. (“Progenics,” “we” or “us”) 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. Our principal programs are directed toward gastroenterology, virology and oncology.

Progenics was incorporated in Delaware in 1986 and commenced principal operations in late 1988. Currently, all of our operations are conducted at our facilities in Tarrytown, New York. Our chief operating decision maker reviews financial analyses and forecasts relating to all of our research programs as a single unit and allocates resources and assesses performance of such programs as a whole. We operate under a single research and development segment.

Gastroenterology

Our lead product is RELISTOR® (methylnaltrexone bromide). In April 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”), commenced sales of RELISTOR subcutaneous injection in the U.S. in June 2008.

Prior to U.S. approval in April 2008, RELISTOR subcutaneous injection had received marketing approval in March 2008 from Health Canada for the treatment of OIC in patients with advanced illness receiving palliative care, and in July 2008, it received marketing approval from the European Commission for the treatment of OIC in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. Commercial launches have begun in these areas. 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 budget, and (iv) have received and will receive royalties and commercialization milestone payments. Manufacturing and commercialization expenses for RELISTOR are funded by Wyeth. Wyeth has elected, as it was entitled to do under the Collaboration Agreement, not to develop RELISTOR in Japan, and as provided in that Agreement returned to us the rights to RELISTOR in Japan. As discussed below, we have out-licensed the rights to subcutaneous RELISTOR in Japan which we reacquired from Wyeth as a result of its election.

In May 2007, we earned \$9.0 million in milestone payments under the Wyeth Collaboration Agreement 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 from Wyeth for the FDA approval of subcutaneous RELISTOR, and in July 2008, we earned a \$10.0 million milestone payment from Wyeth for European approval of subcutaneous RELISTOR.

We and Wyeth are also developing intravenous and oral formulations of RELISTOR.

In October 2008, we entered into an exclusive license agreement with Ono Pharmaceutical Co., Ltd. (“Ono”), Osaka, Japan under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan. Under that agreement, we are entitled to receive from Ono an upfront payment of \$15.0 million, potential development milestones of up to \$20.0 million, and commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. Ono also has the option to acquire from us the rights to develop and commercialize in Japan other formulations of RELISTOR, including intravenous and oral forms, on terms to be negotiated separately.

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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 the return of the Japanese rights, we will not receive from Wyeth milestone payments that were to be triggered by the development of RELISTOR formulations in Japan. These potential future milestone payments would have totaled \$22.5 million (of which \$7.5 million related to the subcutaneous formulation of RELISTOR and the remainder to the intravenous and oral formulations). Taking these adjustments into account, we now have the potential to receive a total of \$334.0 million in development and commercialization milestone payments from Wyeth under the Collaboration Agreement, of which \$39.0 million have been paid to date.

The payments described above will depend on continued success in development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth, Ono, 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.

Virology

In the area of virology, we are developing viral-entry inhibitors for Human Immunodeficiency Virus (“HIV”), the virus that causes AIDS, and for 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, respectively. In May 2007, we announced positive results in HIV-infected individuals from a phase 1b trial examining a single dose of an intravenous formulation of our monoclonal antibody, PRO 140. 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 October 2008, we announced positive interim results from two phase 2 studies, separately evaluating intravenous and subcutaneous dosage forms of PRO 140. Results from all patients enrolled in both of these studies are expected to be obtained in early 2009 and the data are expected to be used to select a dosage form (intravenous or subcutaneous) for further clinical development.

We are also engaged in research regarding a product candidate for HCV, and in November 2008, announced the selection of a proprietary small-molecule drug candidate, designated PRO 206, for clinical development as a treatment of HCV infection. The candidate, an orally available viral-entry inhibitor designed to prevent HCV from entering and infecting healthy liver cells, achieved favorable results in pre-clinical and in vitro studies.

Oncology

In the area of prostate cancer, we are developing a human monoclonal antibody-drug conjugate (“ADC”), consisting of a selectively targeted cytotoxic antibody directed against prostate specific membrane antigen (“PSMA”), a protein found on the surface of prostate cancer cells. In September 2008, we announced the initiation of a phase 1 dose-escalation clinical study to assess PSMA ADC’s safety, tolerability and initial clinical activity. We are also developing therapeutic 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”).

Our virology and oncology product candidates are not as advanced in development as RELISTOR, and we do 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 us for RELISTOR development expenses, we are able to devote our current and future resources to our other research and development programs.

Corporate-Related Matters

We may require additional funding to continue our operations. As a result, we may enter into a collaboration agreement, license or sale transaction or royalty sales or financings with respect to our products and product candidates. We may also seek to raise additional capital through the sale of our common stock or other securities and expect to fund certain aspects of our operations through government grants and contracts.

We have had recurring losses since our inception. At September 30, 2008, we had an accumulated deficit of \$284.1 million and had cash, cash equivalents and marketable securities, including non-current portion, totaling \$134.6 million. We expect that cash, cash equivalents and marketable securities at September 30, 2008 will be sufficient to fund current operations beyond one year. During the nine months ended September 30, 2008, we had a net loss of \$30.1 million and used cash in operating activities of \$32.9 million.

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PROGENICS PHARMACEUTICALS, INC.

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

On April 24, 2008, we announced that our Board of Directors had approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, funding for which will come from the \$15.0 million milestone payment we received from Wyeth for receiving U.S. marketing approval for RELISTOR. Purchases under the program will be made at our 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. During the three months ended September 30, 2008, we have repurchased 200,000 of our outstanding common shares. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have \$12.3 million remaining available for purchases under the program.

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

Our interim Condensed Consolidated Financial Statements 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 our 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. Terms used but not defined herein have the meanings 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. Certain amounts have been reclassified in prior years' financial statements to conform to the current presentation. This included the reclassification of license fees from "Research and development" to "License fees – research and development" which had no effect on total expenses as previously reported.

2. Share-Based Payment Arrangements

On January 1, 2007, we 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 7.3 years, respectively, in 2008 and 5.25 and 7.5 years, respectively, in 2007. Beginning in the third quarter of 2008, we estimated the expected term of stock options granted to our Chief Executive Officer to be 7.5 years. 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. 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 option is based on the U.S. Treasury yield curve in effect at the time of grant.

The assumptions we used in the Black-Scholes option pricing model to estimate the grant date fair values of stock options granted under our stock incentive plans (the "Incentive Plans") during the nine months ended September 30, 2008 and 2007 were as follows:

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For the Nine Months Ended
September 30,
2008 2007

Expected volatility	66% – 91%	52% – 85%
Expected dividends	zero	zero
Expected term (years)	5.33 – 10	5.25 – 10
Weighted average expected term (years)	6.87	6.75
Risk-free rate	2.44%	4.77%
	– 3.79%	– 4.93%

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PROGENICS PHARMACEUTICALS, INC.

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

During the nine months ended September 30, 2008 and 2007, the fair value of shares purchased under the two employee stock purchase plans (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 Incentive Plans, except that the assumptions noted in the following table were used for the Purchase Plans:

	For the Nine Months Ended September 30,	
	2008	2007
Expected volatility	83%	43%
Expected dividends	zero	zero
Expected term	6 months	6 months
Risk-free rate	1.72%	4.78%

The total fair value of shares under all of our share-based payment arrangements that vested during the nine months ended September 30, 2008 and 2007 was \$10.9 million and \$11.8 million, respectively. In such periods; \$5.3 million and \$5.0 million, respectively, of such value was reported as research and development expense, and \$5.6 million and \$6.8 million, respectively, of such value was reported as general and administrative expense.

No tax benefit was recognized related to such compensation cost during the nine months ended September 30, 2008 and 2007 because we had a net loss for each of those periods 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 nine months ended September 30, 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. We incurred a net loss for the three and nine months ended September 30, 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. We have 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 we have net income.

3. 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 (“FAS 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.

Investments consisted of the following:

	September 30, 2008	December 31, 2007
Short-term		
Corporate debt securities and securities of government-sponsored entities	\$ 82,796	\$ 81,170
Auction rate securities	1,150	38,830
Total short-term investments	83,946	120,000
Long-term		
Corporate debt securities and securities of government-sponsored entities	26,769	39,947
Auction rate securities	4,184	-
Total long-term investments	30,953	39,947
Total investments	\$ 114,899	\$ 159,947

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PROGENICS PHARMACEUTICALS, INC.

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

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 our financial 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 currently do not expect the adoption of this statement 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.

The following table presents our available-for-sale investments measured at fair value on a recurring basis as of September 30, 2008 classified by the FAS 157 valuation hierarchy (as previously discussed):

Description	Balance at September 30, 2008	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active	Significant Other Observable	Significant Unobservable Inputs

		Markets for Identical Assets (Level 1)	Inputs (Level 2)	(Level 3)
Money market funds	\$ 16,477	\$ 16,477	\$ -	\$ -
Corporate debt securities and securities of government-sponsored entities	109,565	-	109,565	-
Auction rate securities	5,334	-	-	5,334
Total	\$ 131,376	\$ 16,477	\$ 109,565	\$ 5,334

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PROGENICS PHARMACEUTICALS, INC.

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

At September 30, 2008 we hold \$5.3 million in auction rate securities that were originally issued with Aaa/AAA credit ratings, which are classified as Level 3 (4% of total assets measured at fair value). 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 our auction rate securities because sell orders exceeded buy orders, and we were 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 \$4.1 million of securities collateralized by student loan obligations subsidized by the U.S. government and \$1.2 million of investment company preferred stock, and do not include mortgage-backed instruments. As of September 30, 2008, we have 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 instruments.

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 for these securities do not recover, we may be required to record additional unrealized losses in 2008. We believe we will have the ability to hold any auction rate securities for which auctions fail until their markets recover. We do not anticipate having to sell these securities in order to operate our business. 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.

The valuation of auction rate securities we hold is based on Level 3 unobservable inputs which consist of 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, we have determined a temporary impairment in the valuation of these securities of \$0.3 million, recorded for the three months ended March 31, 2008, which is reflected as a part of other comprehensive loss on our balance sheet. These securities are held “available-for-sale” in conformity with FAS 115 and the unrealized loss is included in other comprehensive loss 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, we have classified these auction rate securities as long-term assets on our balance sheet.

For those financial instruments with significant Level 3 inputs (all of which are auction rate securities), the following tables summarize the activities for the three and nine month periods ended September 30, 2008:

Description	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	For the Three Months Ended September 30, 2008	For the Nine Months Ended September 30, 2008
Balance at beginning of period	\$ 6,042	\$ -

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Transfers into Level 3	-	8,150
Total realized/unrealized gains (losses)		
Included in net loss	-	-
Included in comprehensive income (loss)	92	(316)
Settlements	(800)	(2,500)
Balance at end of period	\$ 5,334	\$ 5,334
Total amount of unrealized gains (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	\$ 92	\$ (316)

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4. Prepaid Research and Development

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 January 1, 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 adoption of EITF 07-3 did not have a material impact on our financial position or results of operations.

5. Accounts Receivable

	September 30, 2008	December 31, 2007
Research and development from collaborator	\$ 5,898	\$ -
Royalties	117	-
National Institutes of Health	804	1,956
Other	13	39
Total	\$ 6,832	\$ 1,995

6. Accounts Payable and Accrued Expenses

	September 30, 2008	December 31, 2007
Accounts payable	\$ 942	\$ 1,158
Accrued consulting and clinical trial costs	6,769	10,848
Accrued payroll and related costs	2,633	1,489
Legal and professional fees	1,055	1,127
Other	17	143
Total	\$ 11,416	\$ 14,765

7. Revenue Recognition

On December 23, 2005, we entered into the Collaboration Agreement with Wyeth for the purpose of developing and commercializing RELISTOR. The Collaboration Agreement involves three formulations of RELISTOR: (i) a subcutaneous formulation to be used in patients with opioid-induced constipation, (ii) an oral formulation to be used in patients with opioid-induced constipation, and (iii) an intravenous formulation to be used in patients with post-operative ileus.

The collaboration is being administered by a Joint Steering Committee (“JSC”) and a Joint Development Committee (“JDC”), each with equal representation by the parties. The JSC is responsible for coordinating the key activities of Wyeth and us under the Collaboration Agreement. The JDC is responsible for overseeing, coordinating and expediting the development of RELISTOR by the parties. In addition, a Joint Commercialization Committee (“JCC”) and Joint Communications Committee (“JComm”) were established, composed of representatives of both Wyeth and us in number and function according to each of our responsibilities. These committees are responsible for facilitating open communication between Wyeth and us on matters relating to the commercialization of RELISTOR approved products and communication about RELISTOR approved products or RELISTOR product candidates in development.

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We have assessed the nature of our involvement with the committees. Our involvement in the JSC and JDC 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 period during which we have developmental responsibilities, however, we have assessed that the nature of our involvement with the committees will be a right, rather than an obligation. Our assessment is based upon the fact that we negotiated to be on the committees as an accommodation for our granting of the license for RELISTOR to Wyeth. 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. During that period, the activities of the committees will be focused on Wyeth's development and commercialization obligations.

Under the Collaboration Agreement, we granted to Wyeth an exclusive, worldwide license, even as to us, to develop and commercialize RELISTOR. Wyeth returned the rights with respect to Japan to us in connection with its election not to develop RELISTOR there and the transaction with Ono discussed in Note 1, above. We and Wyeth are responsible for developing the subcutaneous and intravenous formulations in the U.S., until the drug formulations receive regulatory approval. We have transferred to Wyeth all existing supply agreements with third parties for RELISTOR and have 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. We have no further manufacturing obligations under the Collaboration Agreement. We have and will continue to transfer to Wyeth all know-how, as defined, related to RELISTOR. Based upon our research and development programs, such period will cease upon completion of our development obligations under the Collaboration Agreement.

Wyeth is responsible for the development of the oral formulation worldwide excluding Japan and, the intravenous and subcutaneous formulations outside the U.S., other than Japan. In the event the JSC approves for development 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. Wyeth is also responsible for the commercialization of the subcutaneous, intravenous and oral products, and any other methylnaltrexone based products developed upon approval by the JSC, throughout the world excluding Japan. 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 us. Decisions with respect to commercialization of any products developed under the Collaboration Agreement will be made solely by Wyeth.

Wyeth granted to us 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, at any time, subject to certain conditions. We may exercise this option on an annual basis. We did not exercise the option in connection with the initial commercialization of RELISTOR, and as of September 30, 2008 have not determined when we will exercise it, if at all. The extent of our co-promotion activities and the fee that we will be paid by Wyeth for these activities will be established if, as and when we exercise our option. Wyeth will record all sales of products worldwide (including those sold by us, if any, under a Co-Promotion Agreement). Wyeth may terminate any Co-Promotion Agreement if a top 15 pharmaceutical company acquires control of us. Our potential right to commercialize any product, including our Co-Promotion Option, is not essential to the usefulness of the already delivered products or services (i.e., our development obligations) and our failure to fulfill our co-promotion obligations would not result in a full or partial

refund of any payments made by Wyeth to us or reduce the consideration due to us by Wyeth or give Wyeth the right to reject the products or services previously delivered by us.

We are 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 our 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 of RELISTOR in the U.S., represent one unit of accounting since none of those components has 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.

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Within five business days of execution of the Collaboration Agreement, Wyeth made a non-refundable, non-creditable upfront payment of \$60 million, for which we deferred revenue at December 31, 2005. Subsequently, we are 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. We expect that period to extend through 2009. We are recognizing revenue using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Collaboration Agreement 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 us 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 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. If Wyeth terminates the Collaboration Agreement in accordance with its terms, we will recognize any unamortized remainder of the upfront payment at the time of the termination.

The amount of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 was based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amount of revenue recognized in those periods. During the third quarter of 2007, 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 during the three and nine months ended September 30, 2008 declined relative to that in the comparable periods of 2007.

Beginning in January 2006, costs for the development of RELISTOR incurred by Wyeth or us are being paid by Wyeth. 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. We are recognizing as research and development revenue from collaborator, amounts received from Wyeth for reimbursement of our development expenses for RELISTOR as incurred under the development plan agreed to between us and Wyeth. In addition to the upfront payment and reimbursement of our development costs, Wyeth has made or will make the following payments to us, provided specific milestones, including clinical, regulatory and sales events, are reached, and taking in to account the modifications made in connection with the Ono transaction discussed in Note 1, above: (i) development and sales milestones and contingent payments, consisting of defined non-refundable, non-creditable payments, totaling \$334.0 million, in respect of clinical and regulatory events and, for each form approved as a commercial product, combined annual worldwide (excluding Japan) 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 (excluding Japan). Upon achievement of defined substantive development milestones by us for the subcutaneous and intravenous formulations, the milestone payments will be recognized as revenue. Recognition of revenue for developmental

contingent events related to the oral formulation, which is the responsibility of Wyeth, will be recognized as revenue when Wyeth achieves those events, if they occur subsequent to completion by us of our development obligations, since we would have no further obligations related to those products. Otherwise, if Wyeth achieves any of those events before we have completed our development obligations, recognition of revenue for the Wyeth contingent events will be recognized over the period from receipt of the milestone payment to the completion of our development obligations. All sales milestones will be recognized as revenue when earned.

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During the three and nine month periods ended September 30, 2008, we recognized \$2.1 million and \$8.1 million, respectively, of revenue from the \$60 million upfront payment and \$3.9 million and \$21.8 million, respectively, as reimbursement for our out-of-pocket development costs, including our labor costs. In May 2007, April 2008 and July 2008, we earned \$9.0 million, \$15.0 million and \$10.0 million, respectively, 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 FDA approval of subcutaneous RELISTOR in the U.S. and the European approval of subcutaneous formulation of RELISTOR, respectively. We 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 17, 28 and 31 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. As of September 30, 2008, relative to the \$60 million upfront license payment received from Wyeth, we have recorded \$13.9 million as deferred revenue – current and \$2.8 million as deferred revenue – long term, which is expected to be recognized as revenue over the period of our development obligations relating to RELISTOR. In addition, at September 30, 2008, we recorded \$5.9 million as revenue receivable related to reimbursements from Wyeth for development costs.

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 providing for the royalty. If royalties are received when we have remaining performance obligations, they would be attributed to the services being provided under the arrangement and, therefore, recognized as such obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies above.

In addition, during the three and nine months ended September 30, 2008, we earned \$117 and \$438 of royalty receivables, based on the net sales of subcutaneous RELISTOR, as defined. During the three and nine months ended September 30, 2008, we recognized \$44 and \$86, respectively, of royalty income. As of September 30, 2008, we have recorded a cumulative total of \$352 as deferred revenue (\$293 in deferred revenue – current and \$59 in deferred revenue – long term). The \$352 of deferred royalty revenue is expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR. We incurred \$12 and \$44, respectively, of royalty costs during the three and nine month periods ended September 30, 2008. During the three and nine months ended September 30, 2008, we recognized \$5 and \$9, respectively, of royalty expenses and recorded a cumulative total of \$35 of deferred royalty charges as of September 30, 2008. The \$35 of deferred royalty charges are expected to be recognized as royalty expense over the period of our development obligations relating to RELISTOR.

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. We may terminate the Collaboration Agreement at any time upon 90 days 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 us 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 us. 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.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)
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8. Net Loss Per Share

Our 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 and nine months ended September 30, 2008 and 2007, we 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:

	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Three months ended September 30, 2008			
Basic and Diluted	\$ (12,220)	29,820	\$ (0.41)
Nine months ended September 30, 2008			
Basic and Diluted	\$ (30,074)	29,553	\$ (1.02)
Three months ended September 30, 2007			
Basic and Diluted	\$ (15,600)	26,976	\$ (0.58)
Nine months ended September 30, 2007			
Basic and Diluted	\$ (28,416)	26,639	\$ (1.07)

For the three and nine months ended September 30, 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:

	For the Three Months Ended September 30, 2008		2007	
	Wtd. Avg. Number	Wtd. Avg. Exercise Price	Wtd. Avg. Number	Wtd. Avg. Exercise Price
Stock options	5,071	\$ 17.87	4,832	\$ 17.90
Nonvested shares	534		512	
Total	5,605		5,344	

	For the Nine Months Ended September 30, 2008		2007	
	Wtd. Avg. Number	Wtd. Avg. Exercise Price	Wtd. Avg. Number	Wtd. Avg. Exercise Price
Stock options	4,826	\$ 18.03	4,688	\$ 17.36
Nonvested shares	518		428	
Total	5,344		5,116	

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PROGENICS PHARMACEUTICALS, INC.

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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. Our comprehensive loss includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. For the three and nine months ended September 30, 2008 and 2007, the components of comprehensive loss were:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	\$ (12,220)	\$ (15,600)	\$ (30,074)	\$ (28,416)
Change in net unrealized loss on marketable securities	(2,161)	206	(2,656)	136
Comprehensive loss	\$ (14,381)	\$ (15,394)	\$ (32,730)	\$ (28,280)

10. Commitments and Contingencies

In the ordinary course of our business, we enter into agreements with third parties that include indemnification provisions which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to our products or product candidates, use of such products or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is not limited. We have 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, we have no liabilities recorded for these provisions as of September 30, 2008.

11. Impact of Recently Issued Accounting Standards

In March 2008, the 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. The enhanced disclosure conveys the purpose of derivative use to enable investors a better understanding of 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 impact of the adoption of FAS 161 to have a material effect on our financial position or results of operations.

In October 2008, the FASB issued FASB Staff Position No. FAS 157-3 (“FSP FAS 157-3”), “Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active.” FSP FAS 157-3 clarifies the application of SFAS

157 in a market that is not active and illustrates how an entity should determine fair value when the market for a financial asset is not active. FSP FAS 157-3 provides guidance on how an entity's own assumptions about cash flows and discount rates should be considered when measuring fair value when relevant market data do not exist, how observable market information in an inactive or dislocated market affects fair value measurements and how the use of broker and pricing service quotes should be considered when applying fair value measurements. FSP FAS 157-3 is effective immediately as of September 30, 2008 and for all interim and annual periods thereafter. The adoption of FSP FAS 157-3 did not have a material effect on our financial position or results of operations.

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

Special Note Regarding Forward-Looking Statements

This document contains statements that do not relate strictly to historical fact, any of which may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When we use the words "anticipates," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. While it is impossible to identify or predict all such matters, this may result from, among other things, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; clinical trial data on our products and product candidates will be unfavorable; our products will not receive marketing approval from regulators or, if approved, do not gain sufficient market acceptance to justify development and commercialization costs; we, our collaborators or others might identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not originating from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, declining sales or other adverse events.

We are also subject to risks and uncertainties associated with the actions of our corporate, academic and other collaborators and government regulatory agencies; potential product liability; intellectual property, litigation, environmental and other risks; the risk that licenses to intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.

Risks and uncertainties also include general economic conditions, including interest and currency exchange rate fluctuations and the availability of capital; changes in generally accepted accounting principles; the impact of legislation and regulatory compliance; the highly regulated nature of our business, including government cost-containment initiatives and restrictions on third-party payments for our products; trade buying patterns; the competitive climate of our industry; and other factors set forth in our Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission. In particular, we cannot assure you that our lead product, RELISTOR®, will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, or that any of our other programs will result in a commercial product.

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

Overview

General and Outlook

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 have only recently begun to derive revenue from a commercial product. In order to commercialize the principal products that we have under development, we have been and continue to address a number of technological and clinical challenges and comply with comprehensive U.S. and non-U.S. regulatory requirements. 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.

Gastroenterology

Our lead product is RELISTOR (methylnaltrexone bromide). In April 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"), launched the sale of RELISTOR subcutaneous injection in the U.S. in June 2008.

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Prior to U.S. approval in April 2008, RELISTOR subcutaneous injection had received marketing approval in March 2008 from Health Canada for the treatment of OIC in patients with advanced illness receiving palliative care, and in July 2008, it received marketing approval from the European Commission for the treatment of OIC in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. Commercial launches have begun in these areas. 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 budget, and (iv) have received, and will receive, royalties and commercialization milestone payments. These payments will depend on continued success in 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 are funded by Wyeth. Wyeth has elected, as it was entitled to do under the Collaboration Agreement, not to develop RELISTOR in Japan, and as provided in that Agreement returned to us the rights to RELISTOR in Japan. As discussed below, we have out-licensed the rights to subcutaneous RELISTOR in Japan which we reacquired from Wyeth as a result of its election.

In May 2007, we earned \$9.0 million in milestone payments under Wyeth Collaboration Agreement 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 from Wyeth for the FDA approval of subcutaneous RELISTOR, and in July 2008, we earned a \$10.0 million milestone payment from Wyeth for European 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 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 led the second phase 3 trial of intravenous methylnaltrexone for management of POI, which was similar in design to the Wyeth study. As previously announced, this second study did not meet the primary or secondary end points, confirming the earlier findings of the Wyeth phase 3 intravenous POI study. Progenics and Wyeth are analyzing the results of both studies to determine whether and how to continue development of this formulation of RELISTOR for this indication.

In addition, the companies are currently conducting a third phase 3 trial evaluating an intravenous formulation of RELISTOR in patients following abdominal hernia repair.

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. Commencing in October 2007, two proprietary oral formulations of RELISTOR were tested in separate four-week, double-blind, randomized, placebo-controlled phase 2 trials each consisting of approximately 120 patients with chronic, non-malignant pain who were receiving opioids for pain management. In comparing the activity and tolerability of these oral formulations of RELISTOR, both were generally well tolerated; however, one formulation was identified as having a more favorable clinical profile, while the other did not demonstrate sufficient clinical activity to warrant its continued study. As previously announced, the formulation with the more favorable clinical profile demonstrated statistically significant results after once daily dosing, as assessed by the occurrence of spontaneous bowel movements and other efficacy measures. Further improvement upon this oral formulation through clinical optimization studies is ongoing, with next steps in the development plan for oral RELISTOR to be decided in early 2009.

Finally, the companies are also developing the subcutaneous form of RELISTOR for the treatment of OIC in patients with chronic pain. In the third quarter of 2008, enrollment was completed in a phase 3 clinical study of the subcutaneous form of RELISTOR for the treatment of OIC in patients with chronic pain not related to cancer, such as chronic severe back pain.

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At inception of the Collaboration Agreement, Wyeth paid to us a \$60 million non-refundable upfront payment. Wyeth has made \$39.0 million in milestone payments since that time and is obligated to make up to \$295.0 million in additional payments to us upon the achievement of milestones and contingent events in the development and commercialization of RELISTOR, taking into account the Ono transaction discussed below and in Note 1, above. 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 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 net sales of RELISTOR by Wyeth throughout the world during the applicable royalty periods.

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. Starting June 2008, we began recognizing royalty income based on the net sales of RELISTOR, as defined, by Wyeth.

In October 2008, we entered into an exclusive license agreement with Ono Pharmaceutical Co., Ltd. ("Ono"), Osaka, Japan under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan. Under that agreement, we are entitled to receive from Ono an upfront payment of \$15.0 million, potential development milestones of up to \$20.0 million, and commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. These payments will depend on continued success in development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth, Ono, 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. Ono also has the option to acquire from us the rights to develop and commercialize in Japan other formulations of RELISTOR, including intravenous and oral forms, on terms to be negotiated separately. Supervision of and consultation with respect to Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us.

As a result of the return of the Japanese rights, we will not receive from Wyeth milestone payments that were to be triggered by the development of RELISTOR formulations in Japan. These potential future milestone payments would have totaled \$22.5 million (of which \$7.5 million related to the subcutaneous formulation of RELISTOR and the remainder to the intravenous and oral formulations). Taking these adjustments into account, we now have the potential to receive a total of \$334.0 million in development and commercialization milestone payments from Wyeth under the Collaboration Agreement, of which \$39.0 million have been paid to date.

Virology

In the area of virology, we are developing viral-entry inhibitors for Human Immunodeficiency Virus ("HIV"), the virus that causes AIDS, and for 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, respectively. In May 2007, we announced positive results in HIV-infected individuals from a phase 1b trial examining a single dose of an intravenous formulation of our monoclonal antibody, PRO 140. 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 October 2008, we announced positive interim results from two phase 2 studies, separately evaluating intravenous and subcutaneous dosage forms of PRO 140. Results from all patients enrolled in both of these studies are expected to be obtained in early 2009 and the data are expected to be used to select a dosage form (intravenous or subcutaneous) for further clinical development.

We are also engaged in research regarding a product candidate for HCV, and in November 2008, announced the selection of a proprietary small-molecule drug candidate, designated PRO 206, for clinical development as a treatment of HCV infection. The candidate, an orally available viral-entry inhibitor designed to prevent HCV from entering and infecting healthy liver cells, achieved favorable results in pre-clinical and in vitro studies.

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Oncology

In the area of prostate cancer, we are developing a human monoclonal antibody-drug conjugate (“ADC”), consisting of a selectively targeted cytotoxic antibody directed against prostate specific membrane antigen (“PSMA”), a protein found on the surface of prostate cancer cells. In September 2008, we announced the initiation of a phase 1 dose-escalation clinical study to assess PSMA ADC’s safety, tolerability and initial clinical activity. We are also developing therapeutic 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”).

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.

Results of Operations (amounts in thousands)

Revenues:

Our sources of revenue during the three and nine months ended September 30, 2008 and 2007 included our collaboration with Wyeth, which was effective on January 1, 2006, our research grants and contract from the National Institutes of Health (the “NIH”), royalty income from sales of RELISTOR, and, to a small extent, our sale of research reagents.

Sources of Revenue	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2008	2007	Percent Change	2008	2007	Percent Change
Research from collaborator	\$ 16,015	\$ 14,540	10%	\$ 54,896	\$ 52,987	4%
Royalty income	44	-	N/A	86	-	N/A
Research grants and contract	1,377	2,471	(44%)	5,689	7,077	(20%)
Other revenues	61	7	771%	172	48	258%
Total	\$ 17,497	\$ 17,018	3%	\$ 60,843	\$ 60,112	1%

Research revenue from collaborator

Research revenue from collaborator relates to our Collaboration Agreement with Wyeth. From the inception of the Collaboration Agreement through September 30, 2008 we recognized as revenue: (i) in October 2006, \$5,000 milestone payment in connection with the initiation of the first phase 3 clinical trial of intravenous RELISTOR, (ii) in May 2007, \$9,000 in milestone payments related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of RELISTOR in the U.S and European Union, (iii) in April 2008, \$15,000 milestone payment related to the FDA approval of subcutaneous RELISTOR and (iv) in July 2008, \$10,000 milestone payment related to the European approval of subcutaneous formulation of RELISTOR. We have analyzed the facts and circumstances of the five milestones achieved since inception of the Collaboration Agreement through September

30, 2008, and believe that they met those criteria for revenue recognition upon achievement of the respective milestones. See Critical Accounting Policies –Revenue Recognition, below.

During the three months ended September 30, 2008 and 2007, we recognized \$16,015 and \$14,540, respectively, of revenue from Wyeth, consisting of (i) \$2,092 and \$3,219, respectively, of the \$60,000 upfront payment we received upon entering into the Collaboration Agreement in December 2005, (ii) and \$3,923 and \$11,321, respectively, as reimbursement of our development expenses, and (iii) \$10,000 of non-refundable milestone payment in July 2008.

During the nine months ended September 30, 2008 and 2007, we recognized \$54,896 and \$52,987, respectively, of revenue from Wyeth, consisting of (i) \$8,132 and \$13,138, respectively, of the \$60,000 upfront payment we received upon entering into the Collaboration Agreement, (ii) \$21,764 and \$30,849, respectively, as reimbursement of our development expenses, and (iii) \$25,000 and \$9,000, respectively, of non-refundable milestone payments.

From the inception of our Collaboration Agreement through September 30, 2008, we recognized \$43,341 of revenue from the \$60,000 upfront payment, \$96,425 as reimbursement for our development costs, and a total of \$39,000 for non-refundable milestone payments.

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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 three quarters of 2008 declined by \$5,006 as compared to the first three quarters of 2007.

Royalty income

We began earning royalties from net sales by Wyeth of subcutaneous RELISTOR in June 2008. During the three and nine month periods ended September 30, 2008, we earned \$117 and \$438, respectively, of royalty receivables, based on the net sales of RELISTOR, as defined. During the three and nine months ended September 30, 2008, we recognized \$44 and \$86, respectively, of royalty income. As of September 30, 2008, we have recorded a cumulative total of \$352 as deferred revenue (\$293 in deferred revenue – current and \$59 in deferred revenue – long term). The \$352 of deferred royalty revenue is expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR. Our royalties from net sales by Wyeth of RELISTOR, as defined, are based on royalty rates under our Collaboration Agreement. These rates can range up to 30% of U.S. and 25% of foreign net sales at the highest sales levels. Royalty rates will increase on incremental sales as net sales in a calendar year exceed specified levels.

Research grants and contract

In September 2003, we were awarded a contract (the “NIH Contract”) by the NIH to develop a prophylactic vaccine (“ProVax”) 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 \$28,562 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 December 2008 is \$15,509. Funding under this contract includes the payment of an aggregate of \$1,617 in fees, subject to achievement of specified milestones. Through September 30, 2008, we had recognized revenue of \$14,804 from this contract, including \$180 for the achievement of two milestones. We have been informed by the NIH that it has decided to fund the NIH Contract only through December 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.

Revenues from research grants and contract from the NIH decreased to \$1,377 for the three months ended September 30, 2008 from \$2,471 for the same period of 2007; these amounts consisted of \$1,009 and \$1,676, respectively, from grants and \$368 and \$795, respectively, from the NIH Contract for the three months ended September 30, 2008 and 2007. The decrease in grant and contract revenue resulted from fewer reimbursable expenses in 2008 than in 2007 on new and continuing grants.

Revenues from research grants and contract from the NIH decreased to \$5,689 for the nine months ended September 30, 2008 from \$7,077 for the same period of 2007; these amounts consisted of \$4,185 and \$4,256, respectively, from grants and \$1,504 and \$2,821, respectively, from the NIH Contract for the nine months ended September 30, 2008 and 2007. The decrease in grant and contract revenue resulted from fewer reimbursable expenses in 2008 than in 2007 on new and continuing grants.

Other revenues

Other revenues primarily from higher orders for research reagents increased to \$61 for the three months ended September 30, 2008 from \$7 for the three months ended September 30, 2007. Other revenues primarily from higher orders for research reagents increased to \$172 for the nine months ended September 30, 2008 from \$48 for the nine months ended September 30, 2007.

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Expenses:

Research and Development Expenses:

Research and development expenses include scientific labor, supplies, facility costs, clinical trial costs, product manufacturing costs, royalty payments and license fees. Research and development expenses decreased to \$21,788 for the three months ended September 30, 2008 from \$24,247 for the same period of 2007, and decreased to \$69,988 for the nine months ended September 30, 2008 from \$69,999 for the same period of 2007, as follows:

	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Salaries and benefits (cash)	\$ 6,138	\$ 5,939	3%	\$	19,311	\$ 17,876	8%

Three Months: The increase was due to company-wide compensation increases and an increase in average headcount to 195 from 189 for the three months ended September 30, 2008 and 2007, respectively, in the research and development, manufacturing and clinical departments.

Nine Months: The increase was due to compensation increases and an increase in average headcount to 197 from 186 for the nine months ended September 30, 2008 and 2007, respectively, in the same departments.

	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Share-based compensation (non-cash)	\$ 1,789	\$ 1,829	(2%)	\$	5,246	\$ 5,004	5%

Three Months: The decrease was due to non-vested restricted stock award cancellations partially offset by the vesting of awards. (See Critical Accounting Policies – Share-Based Payment Arrangements, below).

Nine Months: The increase was due to restricted stock award vesting partially offset by non-vested cancellations. (See Critical Accounting Policies – Share-Based Payment Arrangements, below).

	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Clinical trial costs	\$ 2,932	\$ 6,124	(52%)	\$	13,834	\$ 14,520	(5%)

Three Months: Decrease in RELISTOR (\$4,153), due to reduced clinical trial activities in the 2008 period and termination of the GMK study in 2007 (\$438). These decreases were partially offset by an increase in HIV (\$1,399) due to increased PRO 140 clinical trial activities in the 2008 period.

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Nine Months: Decrease primarily related to RELISTOR (\$3,041) and Cancer (\$671) due to decreased RELISTOR clinical trial activities in the 2008 period and termination of the GMK study in 2007. These decreases were partially offset by an increase in HIV (\$3,026) due to increased PRO 140 clinical trial activities in the 2008 period.

		Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
		2008	2007		2008	2007	
Laboratory supplies	\$	866	\$ 1,322	(35%)	\$ 3,024	\$ 3,969	(24%)

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Three Months: Decrease in HIV (\$354), due to purchase of less drug supplies in the 2008 period compared to 2007, Cancer (\$20), due to fewer expenses for PSMA and GMK and Other projects (\$82).

Nine Months: Decrease in HIV (\$567), due to purchase of less drug supplies in the 2008 period compared to 2007, Cancer (\$281), due to fewer expenses for PSMA and GMK, Other projects (\$79) and RELISTOR-related costs (\$18).

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2008	2007		2008	2007	
Contract manufacturing and subcontractors	\$ 7,393	\$ 6,008	23%	\$ 18,547	\$ 17,906	4%

Three Months: Increase in HIV (\$3,528) due to manufacturing expenses for PRO 140 in the third quarter of 2008 but not in 2007, partially offset by decreases in Cancer (\$1,077), primarily due to contract manufacturing expenses for PSMA in the third quarter of 2007 but not in 2008, RELISTOR (\$906), and Other (\$160). 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.

Nine Months: Increase in HIV (\$6,515) due to manufacturing expenses for PRO 140 in the 2008 period but not in 2007, and Other projects (\$552), partially offset by decreases in Cancer (\$5,370) primarily due to contract manufacturing expenses for PSMA in the nine months of 2007 but not in 2008 and RELISTOR (\$1,056). 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.

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2008	2007		2008	2007	
Consultants	\$ 529	\$ 934	(43%)	\$ 3,013	\$ 3,636	(17%)

Three Months: Decreases in RELISTOR (\$295), Cancer (\$20), HIV (\$57) and Other projects (\$33). These expenses are related to the monitoring of clinical trials as well as 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.

Nine Months: Decrease in RELISTOR (\$973) and Other (\$7), partially offset by increases in Cancer (\$244) and HIV (\$113). These expenses are related to the monitoring of clinical trials as well as 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 September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2008	2007		2008	2007	

License fees	\$	305	\$	(16)	2,006%	\$	1,788	\$	833	115%
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Three Months: Increase primarily due to HIV (\$133) and RELISTOR (\$188) expenses in 2008 and a reduction in the amount due in 2007 related to our HIV program.

Nine Months: Increase primarily related to payments in the 2008 period related to HIV (\$1,108) and RELISTOR (\$231), partially offset by a decrease in Cancer (\$384).

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	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2008	2007		2008	2007	
Royalty expense	\$ 5	-	N/A	\$ 9	-	N/A

Three Months: We incurred \$12 of royalty costs and recognized \$5 of royalty expenses during the three months ended September 30, 2008. As of September 30, 2008, we recorded a cumulative total of \$35 of deferred royalty charges from the royalty costs incurred in the second and third quarters of 2008. The \$35 of deferred royalty charges are expected to be recognized as royalty expense over the period of our development obligations relating to RELISTOR.

Nine Months: We incurred \$44 of royalty costs and recognized \$9 of royalty expenses during the nine month period ended September 30, 2008. As of September 30, 2008, we recorded a cumulative total of \$35 of deferred royalty charges from the royalty costs incurred in the second and third quarters of 2008. The \$35 of deferred royalty charges are expected to be recognized as royalty expense over the period of our development obligations relating to RELISTOR.

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2008	2007		2008	2007	
Other operating expenses	\$ 1,831	\$ 2,107	(13%)	\$ 5,216	\$ 6,255	(17%)

Three Months: Decrease primarily in computer expenses (\$150), facilities (\$26), insurance (\$75) and travel (\$74), partially offset by an increase in other operating expenses (\$45) and rent (\$4).

Nine Months: Decrease primarily in computer expenses (\$1,295), insurance (\$251) and other (\$72) partially offset by an increase in rent (\$579).

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 decreased to \$8,265 for the three months ended September 30, 2008 from \$9,275 for the same period of 2007 and increased to \$22,530 for the nine months ended September 30, 2008 from \$21,746 for the same period of 2007, as follows:

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2008	2007		2008	2007	
	\$ 2,316	\$ 1,641	41%	\$ 6,892	\$ 5,418	27%

Salaries and benefits
(cash)

Three Months: Increase due to compensation increases and an increase in average headcount to 55 from 42 in the general and administrative departments between the periods.

Nine Months: Increase due to compensation increases and an increase in average headcount to 52 from 42 in the general and administrative departments between the periods.

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	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Share-based compensation (non-cash)	\$ 2,324	\$ 4,337	(46%)	\$	5,654	\$ 6,836	(17%)

Three and Nine Months: The decrease was due to non-vested restricted stock award cancellations partially offset by the vesting of awards. (See Critical Accounting Policies – Share-Based Payment Arrangements, below).

	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Consulting and professional fees	\$ 2,220	\$ 1,656	34%	\$	5,734	\$ 5,009	15%

Three Months: Increase due primarily to increases in consulting (\$703), audit and tax fees (\$64) and other (\$54), partially offset by a decrease in legal and patent fees (\$257).

Nine Months: Increase due primarily to increases in consulting (\$465), legal and patent fees (\$192) and miscellaneous costs (\$98), partially offset by a decrease in audit and tax fees (\$30).

	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Other operating expenses	\$ 1,405	\$ 1,641	(14%)	\$	4,250	\$ 4,483	(5%)

Three Months: Decrease in facility costs (\$188), recruiting (\$152), conferences and seminars (\$22) and investor relations (\$25), partially offset by increases in insurance (\$47), taxes (\$57) and other (\$47).

Nine Months: Decrease in facility costs (\$279), investor relations (\$55) and other (\$142), partially offset by increases in rent (\$189), conferences and seminars (\$21) and taxes (\$33).

	Three Months Ended September 30,		Percent Change		Nine Months Ended September 30,		Percent Change
	2008	2007			2008	2007	
Depreciation and amortization	\$ 1,166	\$ 845	38%	\$	3,427	\$ 2,144	60%

Three Months: Depreciation expense increased to \$1,166 for the three months ended September 30, 2008 from \$845 for the same period of 2007, due to purchases of capital assets and additional leasehold improvements made after September 30, 2007.

Nine Months: Depreciation expense increased to \$3,427 for the nine months ended September 30, 2008 from \$2,144 for the same period of 2007 due to purchases of capital assets and additional leasehold improvements made after September 30, 2007.

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	Three Months Ended September 30, 2008		September 30, 2007		Percent Change	Nine Months Ended September 30, 2008		September 30, 2007		Percent Change
Other income	\$	1,502	\$	1,749	(14%)	\$	5,028	\$	5,361	(6%)

Three Months: Interest income decreased to \$1,502 for the three months ended September 30, 2008 from \$1,749 for the same period of 2007. Interest income, as reported, is primarily the result of investment income from our marketable securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those marketable securities. For the three months ended September 30, 2008 and 2007, investment income increased to \$1,816 from \$1,618, 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 (\$314) from \$131 for the three months ended September 30, 2008 and 2007, respectively.

Nine Months: Interest income decreased to \$5,028 for the nine months ended September 30, 2008 from \$5,361 for the same period of 2007. Interest income, as reported, is primarily the result of investment income from our marketable securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those marketable securities. For the nine months ended September 30, 2008 and 2007, investment income increased to \$5,648 from \$5,007, 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 (\$620) from \$354 for the nine months ended September 30, 2008 and 2007, respectively.

Net Loss:

Net loss was \$12,220 for the three months ended September 30, 2008 compared to \$15,600 for the same period of 2007, and \$30,074 for the nine months ended September 30, 2008 compared to \$28,416 for the same period of 2007.

Liquidity and Capital Resources

Overview

We have to date generated only modest amounts of product and royalty revenue, and consequently have relied principally on external funding and our Collaboration Agreement with Wyeth to finance our operations. We have funded 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, proceeds from the exercise of outstanding options and warrants and sale of our common stock under our two employee stock purchase plans (the "Purchase Plans"). At September 30, 2008, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$134.6 million compared with \$170.4 million at December 31, 2007. We expect that our existing cash, cash equivalents and marketable securities at September 30, 2008 will be sufficient to fund current operations for at least one year. Our cash flow from operating activities was negative for the nine-month periods ended September 30, 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, which is currently expected to continue through 2009. For the nine months ended September 30, 2008 and 2007, we received \$21.8 million and \$30.8 million, respectively, of such reimbursement. Since inception of the Collaboration Agreement, Wyeth has made \$39.0 million in milestone payments to us upon the achievement of certain events. 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 the U.S. application in April 2008 resulted in our earning a \$15.0 million milestone payment, which was recognized in the second quarter of 2008. In July 2008, we earned \$10.0 million milestone payment for the European approval of subcutaneous RELISTOR. Wyeth has also submitted applications for the marketing of RELISTOR 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 \$295 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, other than that to be conducted by Ono. We will receive royalty payments from Wyeth as the product is sold in the various countries (other than Japan) where marketing approval has been obtained. We will also receive royalty payments upon the sale of all other products developed under the Collaboration Agreement.

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Under our license agreement with Ono, we are entitled to receive from Ono the upfront and milestone payments described above, as well as royalties on sales of subcutaneous RELISTOR in Japan. Ono is also responsible for development and commercialization costs for subcutaneous RELISTOR in Japan.

The funding by Wyeth and Ono of development costs for RELISTOR generally enhances our ability to devote current and future resources to other research and development programs. We may also enter into other collaboration agreements, license or sale transactions or royalty sales or financings with respect to our products and product candidates. We cannot forecast with any degree of certainty, however, which products or indications, if any, will be subject to future arrangements, or how they would affect our capital requirements. The consummation of other agreements would further allow us to advance other projects with 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 December 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 September 30, 2008, we had recognized revenue of \$14.8 million from this contract, including \$0.2 million for the achievement of two milestones. We have been informed by the NIH that it has decided to fund this contract only through December 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.

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 made during 2005, provide for up to \$3.0 million and \$9.7 million in support of our HCV research program and PRO 140 HIV development programs 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 nine months ended September 30, 2008 and 2007, we recognized \$4.2 million and \$4.3 million, respectively, of revenue from all of our NIH grants.

Changes in Accounts receivable and Accounts payable for the nine months ended September 30, 2008 from the same period of 2007 resulted from the timing of receipts from the NIH and Wyeth, and payments made to trade vendors in the normal course of business.

Other than amounts to be received from Wyeth, Ono 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 product candidates to the commercial marketing stage.

Investing Activities. We purchase and sell marketable securities in order to provide funding for operations. 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 September 30, 2008, we continue to hold approximately \$5.3

million (4% of total assets measured at fair value) 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 for these securities do not recover, we may be required to record additional unrealized losses in 2008, which may affect our financial condition, cash flows and net loss. 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.

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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 September 30, 2008.

Financing Activities. During the nine months ended September 30, 2008 and 2007, we received cash of \$5.1 million and \$63.2 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants, from the sale of our common stock under our Purchase Plans and from sale of common stock in public offering in 2007. The amount of cash we receive from these sources fluctuates commensurate with 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 the Purchase Plans.

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 relating to our gastroenterology, virology and oncology product candidates, and are conducting several smaller research projects in the areas of virology and oncology. Our total expenses for research and development from inception through September 30, 2008 have been approximately \$487.4 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, 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 \$21.1 million over the period from October 1, 2008 to December 31, 2009.

For the nine months ended September 30, 2008 and 2007, research and development costs incurred by project were as follows:

	For the Nine Months Ended September 30,	
	2008	2007
	(in millions)	
RELISTOR	\$ 22.6	\$ 30.9
HIV	32.6	19.1
Cancer	7.5	13.5
Other programs	7.3	6.5
Total	\$ 70.0	\$ 70.0

We may require additional funding to continue our research and product development programs, conduct pre-clinical studies and clinical trials, fund operating expenses, pursue regulatory approvals for our product candidates, file and prosecute patent applications and enforce or defend patent claims, if any, and fund product in-licensing and any possible acquisitions. Manufacturing and commercialization expenses for RELISTOR will be funded by Wyeth in the U.S. and outside the U.S. except for Japan, where development, manufacturing and commercialization expenses will be funded by Ono. 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 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 the obligation to make 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 to be responsible to make payments (including royalties) to the University of Chicago upon the occurrence of certain events. See Results of Operations – Royalty expenses, above.

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 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.

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Investing Activities. During the nine months ended September 30, 2008 and 2007, we have spent \$2.0 million and \$4.4 million, respectively, on capital expenditures related to the expansion of office, laboratory and manufacturing facilities and the purchase of more laboratory equipment for 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.

Financing Activities. On April 24, 2008, we announced that our Board of Directors had approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, funding for which will come from the \$15.0 million milestone payment we received from Wyeth for receiving U.S. marketing approval for RELISTOR. Purchases under the program will be made at our 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. During the three months ended September 30, 2008, we have repurchased 200,000 of our outstanding common shares for a total of \$2.7 million. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have \$12.3 million remaining available for purchases under the program.

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 September 30, 2008 for future payments under these agreements:

	Total	2009	Payments due by September 30, (in millions)			
			2010-2011	2012-2013	Thereafter	
Operating leases	\$ 5.7	\$ 3.1	\$ 1.7	\$ 0.7	\$ 0.2	
License and collaboration agreements (1)	89.3	2.0	5.9	13.6	67.8	
Total	\$ 95.0	\$ 5.1	\$ 7.6	\$ 14.3	\$ 68.0	

- (1) Assumes attainment of milestones covered under each agreement, including those by PSMA LLC. Timing of achievement of 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.

We periodically assess the scientific progress and merits of each of our 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 prospects for ultimate commercialization. Because of the uncertainties associated with research and development in 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 research and development projects in a timely manner or failure to enter into collaborative agreements could significantly increase capital requirements and adversely affect 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.

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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.

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 nine months ended September 30, 2008 and 2007, we also recognized revenue from government research grants and contract, which are used to subsidize a portion of certain of our research 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 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.

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During the course of a collaboration agreement, e.g., the Collaboration Agreement, 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, 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.

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, we have assessed the nature of our involvement with the JSC, JDC, JCC and JComm. 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 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. As discussed in Overview – Gastroenterology, Wyeth returned the rights to RELISTOR with respect to Japan to us in connection with its election not to develop RELISTOR there and the transaction with Ono. As a result, Wyeth is now responsible for the development of the oral formulation worldwide excluding Japan and the intravenous and subcutaneous formulations outside the U.S., other than Japan.

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, May 2007, April 2008 and July 2008, we earned \$5.0 million, \$9.0 million, \$15.0 million and \$10.0 million, respectively, upon achievement of non-refundable milestones anticipated in the Collaboration Agreement; the first in connection with the commencement of a phase 3 clinical trial of the intravenous formulation of RELISTOR, 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, the third for the FDA approval of subcutaneous RELISTOR and the fourth for the European approval of subcutaneous RELISTOR. 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 or the risk associated with the achievement of these milestones; and the passage of ten, 17, 28 and 31 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.

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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 based upon net sales of related licensed products, as reported to us by Wyeth. Royalty revenue is recognized in the period the sales occur, 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 providing for the royalty. If royalties are received when we have remaining performance obligations, they would be attributed to the services being provided under the arrangement and, therefore, recognized as such obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

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 (non-vested shares) and shares issued under our 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 (non-vested 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.

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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. For this purpose:

- 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 nine months ended September 30, 2008 and 2007, the volatility of our common stock has been high, 66% - 91% and 52% - 85%, 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 nine months ended September 30, 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 7.3 years and 5.25 and 7.5 years, respectively. Beginning in the third quarter of 2008, we estimated the expected term of stock options granted to our Chief Executive Officer to be 7.5 years. 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. For the July 1, 2008 award, the Compensation Committee of the Board of Directors modified the form of the grant used for stock incentive awards to provide for vesting of stock incentive awards granted on that date ratably over a three-year period and for acceleration of the vesting of such awards and all previously granted and outstanding awards for any employee in the event that, following a Change in Control, such employee's employment is Terminated without Cause (as such terms are defined in our 2005 Stock Incentive Plan).
- Since we have never paid dividends and do not expect to pay dividends in the future, 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, 2004, on July 3, 2006 and on July 2, 2007 cliff vests after nine years and eleven months from the respective grant date. The July 1, 2002, 2003 and 2005 awards have been fully vested. 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). On July 1, 2008, we granted options and restricted stock to our employees, including grants to our Chief Executive

Officer. The options have an exercise price equal to the closing price on our common stock on the date of grant and vest ratably over a three-year period (except in the case of our Chief Executive Officer, which vest on the basis of the achievement of specified performance based milestones). Compensation expense, for the July 1, 2008 award, will be recognized ratably over the vesting period, however, the portion of the award to our Chief Executive Officer will be recognized over the shortest estimated time for the achievement of the performance or market conditions. Changes in the estimate of probability of achievement of any performance or market condition will be reflected in compensation expense of the period of change and future periods affected by the change.

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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 nine months ended September 30, 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 nine months ended September 30, 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 nine months ended September 30, 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. The Collaboration Agreement with Wyeth 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 January 1, 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 adoption of EITF 07-3 did not have a material impact on the financial position or results of operations.

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 loss.

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 our financial assets or liabilities.

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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 currently do not expect the adoption of this statement 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 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. The enhanced disclosure conveys the purpose of derivative use to enable investors a better understanding of 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.

In October 2008, the FASB issued FASB Staff Position No. FAS 157-3 (“FSP FAS 157-3”), “Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active.” FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active and illustrates how an entity should determine fair value when the market for a financial asset is not active. FSP FAS 157-3 provides guidance on how an entity’s own assumptions about cash flows and discount rates should be considered when measuring fair value when relevant market data do not exist, how observable market information in an inactive or dislocated market affects fair value measurements and how the use of broker and pricing service quotes should be considered when applying fair value measurements. FSP FAS 157-3 is effective immediately as of September 30, 2008 and for all interim and annual periods thereafter. The adoption of FSP FAS 157-3 did not have a material effect on our financial position or results of operations.

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 corporate debt securities, securities of government sponsored entities and auction rate securities. Our investments totaled \$131.4 million at September 30, 2008. Approximately \$109.6 million of these investments had fixed interest rates, and \$21.8 million had interest rates that were variable. Our marketable securities are classified as available-for-sale.

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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 September 30, 2008 market interest rates would result in a decrease of approximately \$0.07 million in the market values of these investments.

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 September 30, 2008, we continue to hold approximately \$5.3 million (4% of assets measured at fair value) 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 the auction rate securities 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.

The valuation of the auction rate securities we hold is based on an 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, we have determined a temporary impairment in the valuation of these securities of \$0.3 million for the nine months ended September 30, 2008. A 100 basis point increase to our internal analysis would result in an increase of approximately \$0.042 million in the valuation of these securities as of the nine months ended September 30, 2008.

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 U.S. 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.

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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 and our other public reports. In addition, the following risk factors have changed during the quarter ended September 30, 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. With respect to our recent license agreement with Ono for development and commercialization of subcutaneous RELISTOR in Japan, we will be reliant on Ono to conduct successful clinical trials and obtain regulatory approval in that country. 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' FUZEON™ and Pfizer's SELZENTRY™) 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 are likely to need additional financing, but our access to capital funding is uncertain.

As of September 30, 2008, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$134.6 million. During the nine months ended September 30, 2008, we had a net loss of \$30.1 million and cash used in operating activities was \$32.9 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 three quarters 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. Under our agreement with Ono, Ono is responsible for development and commercialization costs for subcutaneous RELISTOR in Japan.

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, license or sale transactions or royalty sales or financings, 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.

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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 \$15.0 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 September 30, 2008, we continue to hold approximately \$5.3 million (4% of total assets measured at fair value) 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 the market conditions for these securities do not recover, we may be required to record additional unrealized losses in 2008, which may affect our financial condition, cash flows and net loss. 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.

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 GlaxoSmithKline ("GSK"), received FDA approval in May 2008 for ENTEREG® (alvimopan), an oral form of an opioid antagonist, for postoperative ileus, "to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis", and is developing the oral form of alvimopan for opioid-induced bowel dysfunction (which we believe is perceived in the marketplace as being substantially equivalent to "opioid-induced constipation"), which has been the subject of phase 3 clinical trials. We are also aware that Sucampo Pharmaceuticals, Inc., in collaboration with Takeda Pharmaceutical Company Limited, is currently conducting phase 3 pivotal clinical trials of AMITIZA® (lubiprostone) for the treatment of opioid-induced bowel dysfunction. Either drug may achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of GSK and Takeda may impair our ability to compete effectively in the market.

Under the terms of our collaboration with Wyeth with respect to RELISTOR, Wyeth is developing the oral formulation of RELISTOR worldwide excluding Japan. We and Wyeth are responsible for 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. other than in Japan, where Ono is developing subcutaneous RELISTOR. Under the Wyeth collaboration, decisions regarding the timelines for development of the three RELISTOR formulations are

being be made by a JDC, and endorsed by the JSC, each committee formed under the terms of the license and co-development agreement, consisting of members from both Wyeth and Progenics. With respect to our collaboration with Ono in Japan, supervision of and consultation regarding Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us.

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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 September 30, 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, and current financial and market conditions have resulted in widespread pressures on securities of issuers throughout the world economy. 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;
- 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 and financial conditions.

Purchases of our common shares pursuant to our recently announced \$15.0 million share repurchase program may, depending on their timing, volume and form, 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.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On April 24, 2008, we announced that our Board of Directors had approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, funding for which will come from the \$15.0 million milestone payment we received from Wyeth for receiving U.S. marketing approval for RELISTOR. Purchases under the program will be made at our 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. During the three months ended September 30, 2008, we have repurchased 200,000 of our outstanding common shares. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have \$12.3 million remaining available for purchases under the program. The following table summarizes the purchases made under this program during the three months ended September 30, 2008:

Month	Total Number of Shares Purchased	Average Price Paid per Share (Includes Commissions)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Amount That May Yet Be Purchased Under the Plan
July	-	\$ -	-	\$ -
August	200,000	13.70	200,000	12,259,300
September	-	-	-	-
Total	200,000	\$ 13.70	200,000	\$ 12,259,300

Item 6. Exhibits

(a) Exhibits

Exhibit
Number

* Description

10.6.1(1) Form of Non-Qualified Stock Option Award Agreement

10.6.2(1) Form of Restricted Stock Award Agreement

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

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

* Exhibits footnoted as previously filed have been filed as an exhibit to the document of the Registrant referenced in the footnote below, and are incorporated by reference herein.

- (1) Previously filed in Current Report on Form 8-K filed on July 8, 2008.

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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.

Date: November 10, 2008

PROGENICS PHARMACEUTICALS, INC.

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)