PROGENICS PHARMACEUTICALS INC

Form 10-Q May 11, 2009

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

Commission File No. 000-23143

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#### 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 Number)

777 Old Saw Mill River Road
Tarrytown, NY 10591
(Address of principal executive offices, including zip code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if

any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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 x Non-accelerated filer " (Do not check if a smaller reporting company) company "	Smaller reporting
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the lAct). Yes o No x	Exchange
As of May 6, 2009 there were 31,022,934 shares of common stock, par value \$.0013 per share, of outstanding.	the registrant

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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)

	Γ	December 31,	N	March 31,
<b>A</b>		2008		2009
Assets				
Current assets:	\$	56,186	\$	62 200
Cash and cash equivalents  Marketable securities	Ф	63,127	Ф	62,288 56,300
Accounts receivable		1,337		692
Other current assets		3,531		2,774
Total current assets		124,181		122,054
Marketable securities		22,061		9,108
Fixed assets, at cost, net of accumulated depreciation and amortization		11,071		10,464
Restricted cash		520		520
Total assets	\$	157,833	\$	142,146
Total assets	Ψ	137,633	Ψ	142,140
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	6,496	\$	6,379
Deferred revenue - current		31,645		12,005
Other current liabilities		57		57
Total current liabilities		38,198		18,441
Other liabilities		266		242
Total liabilities		38,464		18,683
Commitments and contingencies (Note 9)				
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 — 30,807,387 in				
2008 and 31,082,566 in 2009		40		40
Additional paid-in capital		422,085		427,689
Accumulated deficit		(298,718)		(300,506)
Accumulated other comprehensive loss		(1,297)		(1,019)
Treasury stock, at cost (200,000 shares in 2008 and 2009)		(2,741)		(2,741)
Total stockholders' equity		119,369		123,463
Total liabilities and stockholders' equity	\$	157,833	\$	142,146

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

# PROGENICS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months			
	Ended			
	March 31,			,
		2008		2009
Revenues:				
Research and development	\$	12,110	\$	20,144
Royalty income		-		175
Research grants and contract		2,613		507
Other revenues		39		78
Total revenues		14,762		20,904
Expenses:				
Research and development		22,790		14,830
License fees – research and development		1,149		630
General and administrative		7,152		6,801
Royalty expense		-		18
Depreciation and amortization		1,114		1,203
Total expenses		32,205		23,482
Operating loss		(17,443)		(2,578)
Other income:				
Interest income		1,958		790
Total other income		1,958		790
Net loss	\$	(15,485)	\$	(1,788)
Net loss per share - basic and diluted	\$	(0.52)	\$	(0.06)
Weighted-average shares - basic and diluted		29,789		30,707

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 THREE MONTHS ENDED MARCH 31, 2008 AND 2009

# (amounts in thousands) (Unaudited)

	Commo			Additional Paid-In	Ac	ccumulated Deficit	Accumu Othe Compreho Incon	r ensive	Treasu Shares	ry Stock Amount	Total
Balance at December	Shares	AII	nount	Capital		Deficit	IIICOII	.16	Shares	Amount	Total
31, 2007	29,754	\$	39	\$ 401,500	\$	(254,046)	\$	6	-	\$ -	\$ 147,499
Comprehensive loss:											
Net loss	-		-	-		(15,485)		-	-	-	(15,485)
Net change in unrealized gain on marketable securities				_				386		_	386
Total comprehensive	_					_		300	_	_	300
loss:											(15,099)
Compensation expenses for share-based payment											
arrangements	-		-	3,912		-		_	-	-	3,912
Issuance of restricted stock, net of forfeitures	(2)	)	_	_		_		_	_	_	_
Sale of common stock under employee stock purchase plans and exercise of stock	(=)										
options	157		-	1,538		-		_	-	-	1,538
Balance at March 31, 2008	29,909	\$	39	\$ 406,950	\$	(269,531)	\$	392	_	\$ -	\$ 137,850
	_,,,	7		+ 100,500	7	(===,===)	,			<del>-</del>	,,
	Common	n Sto	ck .	Additional Paid-In	Acc		Accumula Other omprehen (Loss)		Treasur	y Stock	
	Shares	Amo	ount	Capital		Deficit	Income	,	Shares	Amount	Total
Balance at December 31, 2008	30,807	\$	40	\$ 422,085	\$ (	(298,718) \$	\$ (1,2	.97)	(200)	\$ (2,741)	\$119,369

Comprehensive loss:									
Net loss	-		-	-	(1,788)	-	-	-	(1,788)
Net change in unrealized loss on marketable									
securities	_		_	_	-	278	-	-	278
Total comprehensive loss:									(1,510)
Compensation expenses for share-based payment arrangements	_		_	4,143	_	_	_	_	4,143
Issuance of				.,					.,2 .0
restricted stock, net									
of forfeitures	42		-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock									
options	234		-	1,461	-	-	-	-	1,461
Balance at March 31, 2009	31,083	\$ 40	) <b>\$</b>	\$ 427,689	\$ (300,506) \$	(1,019)	(200) \$	(2,741) \$	123,463

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

# PROGENICS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (amounts in thousands) (Unaudited)

	For the Thr	ee N	<b>Months</b>
	Enc	led	
	Marc	h 31	,
	2008		2009
Cash flows from operating activities:			
Net loss	\$ (15,485)	\$	(1,788)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,114		1,203
Write-off of fixed assets	-		1
Amortization of discounts, net of premiums, on marketable securities	95		299
Expenses for share-based compensation awards	3,912		4,143
Changes in assets and liabilities:			
Decrease in accounts receivable	388		645
(Increase) decrease in other current assets	(267)		757
Decrease in accounts payable and accrued expenses	(2,069)		(117)
Decrease in deferred revenue	(4,098)		(19,640)
Decrease in other liabilities	(23)		(24)
Net cash used in operating activities	(16,433)		(14,521)
Cash flows from investing activities:			
Capital expenditures	(797)		(597)
Sales/maturities of marketable securities	63,055		19,759
Purchase of marketable securities	(31,800)		-
Increase in restricted cash	(1)		-
Net cash provided by investing activities	30,457		19,162
Cash flows from financing activities:			
Proceeds from the exercise of stock options and sale of common stock under the			
Employee Stock Purchase Plan	1,538		1,461
Net cash provided by financing activities	1,538		1,461
Net increase in cash and cash equivalents	15,562		6,102
Cash and cash equivalents at beginning of period	10,423		56,186
Cash and cash equivalents at end of period	\$ 25,985	\$	62,288

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 and 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 supportive care, virology and oncology.

Progenics commenced principal operations in 1988, became publicly traded in 1997 and throughout has been engaged primarily in research and development efforts, developing manufacturing capabilities, establishing corporate collaborations and raising capital. We have only recently begun to derive revenue from a commercial product. 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.

Supportive Care. Our first commercial product, RELISTOR® (methylnaltrexone bromide) subcutaneous injection, was approved by the U.S. Food and Drug Administration ("FDA") in April 2008 for sale in the United States. Our collaboration partner, Wyeth Pharmaceuticals ("Wyeth"), commenced sales of RELISTOR subcutaneous injection in June, and we have begun earning royalties on world-wide sales. Regulatory approvals have also been obtained in Canada, the European Union, Australia and Venezuela, and marketing applications have been approved or are pending or scheduled in other countries. In October 2008, we out-licensed to Ono Pharmaceutical Co., Ltd. ("Ono"), Osaka, Japan, the rights to subcutaneous RELISTOR in Japan, where Wyeth elected not to develop the product. We continue development and clinical trials with respect to other indications for RELISTOR.

Development and commercialization of RELISTOR is being conducted under a license and co-development agreement ("Wyeth 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 additional payments as certain developmental milestones for RELISTOR are achieved, (iii) have been and are entitled to 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 are entitled to receive royalties and commercialization milestone payments.

Manufacturing and commercialization expenses for RELISTOR are funded by Wyeth. In January 2009, Wyeth and Pfizer Inc. announced a definitive agreement under which Pfizer is to acquire Wyeth. We understand that the transaction is currently expected to close in late 2009 and is subject to a variety of conditions. The proposed acquisition does not trigger any change-of-control provisions in our collaboration with Wyeth, and if the acquisition is completed in the transaction structure announced by the parties, the combined Pfizer/Wyeth organization will continue to have the same rights and responsibilities under the Collaboration following the acquisition as Wyeth had before. We may not, however, learn of any plans the parties may have for RELISTOR and our Collaboration unless and until or even after the proposed transaction closes.

Under our License Agreement with Ono, we have received an upfront payment of \$15.0 million, and are entitled to receive potential milestones, upon achievement of development responsibilities by Ono, of up to \$20.0 million, 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.

Because Wyeth is not developing RELISTOR in Japan, we will not receive from it Japan-related milestone payments provided in the original Wyeth Collaboration Agreement. 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). As a result, we now have the potential to receive a total of \$334.0 million in development and commercialization milestone payments from Wyeth under the Wyeth Collaboration Agreement (of which \$60.0 million relate to the intravenous formulation of RELISTOR), and of which \$39.0 million (\$5.0 million relating to the intravenous formulation) have been paid to date.

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# PROGENICS PHARMACEUTICALS, INC.

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

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 two viral-entry inhibitors: a humanized monoclonal antibody, PRO 140, for treatment of human immunodeficiency virus ("HIV"), the virus that causes acquired immunodeficiency syndrome ("AIDS"), and a proprietary orally-available small-molecule drug candidate, PRO 206, for treatment of hepatitis C virus infection ("HCV"). Based on results from previous phase 2 clinical trials, we are developing the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for convenient, weekly self-administration, and we are conducting preclinical development activities in preparation for filing an Investigational New Drug ("IND") application for PRO 206. We are also engaged in research regarding prophylactic vaccines against HIV infection.

Oncology. In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal antibody-drug conjugate ("ADC") directed against prostate specific membrane antigen ("PSMA"), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. 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 ("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.

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 awards. We are currently in discussions with government agencies and others to obtain pivotal clinical trial funding to support our PRO 140 compound, and are pursuing strategic collaborations with biopharmaceutical companies to support our development plan for PSMA ADC.

We have had recurring losses since our inception. At March 31, 2009, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$127.7 million which we expect will be sufficient to fund current operations beyond one year. During the three months ended March 31, 2009, we had a net loss of \$1.8 million and used \$14.5 million of cash in operating activities. At March 31, 2009, we had an accumulated deficit of \$300.5 million.

In April 2008, our Board of Directors approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, under which we have \$12.3 million remaining available for purchases. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have not repurchased any of our outstanding common shares during the three months ended March 31, 2009.

Pending use in our business, our revenues and proceeds of financing activities are held in cash, cash equivalents and marketable securities. 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, 2008. 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.

#### PROGENICS PHARMACEUTICALS, INC.

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

### 2. Share-Based Payment Arrangements

We estimate the expected term of stock options granted to employees and officers (excluding our Chief Executive Officer) and directors by using historical data for these two groups. The expected term for options granted to these two groups was 5.33 and 8 years, respectively, in 2008 and 5.3 and 7.3 years, respectively, in the first quarter of 2009. Beginning in the third quarter of 2008, we began estimating the expected term of stock options granted to our Chief Executive Officer separately from stock options granted to employees and officers, and the expected term was 7.8 years in the first quarter of 2009. The expected term for stock options granted to non-employee consultants was ten years, equal to the contractual term of those options. In making these estimates, we calculated the expected volatility based upon the period of the respective expected terms, using a dividend rate of zero (since we have never paid and do not expect to pay dividends in the future) and a risk-free rate for periods within the expected term of the option 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 three months ended March 31, 2008 and 2009 were as follows:

		Months Ended ch 31,
	2008	2009
Expected volatility	66% – 90%	71% – 91%
Expected dividends	zero	zero
Expected term (years)	5.33 - 10	5.3 - 10
Weighted average expected term (years)	5.58	7.1
Risk-free rate	3.08% - 3.71%	1.78% - 2.68%

During the three months ended March 31, 2008 and 2009, 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 Financial Accounting Standards Board ("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, but with the following assumptions:

	For the Three	Months Ended
	Marc	h 31,
	2008	2009
Expected volatility	154%	100%
Expected dividends	zero	zero
Expected term	6 months	6 months
Risk-free rate	2.74%	0.38%

The total fair value of shares under all of our share-based payment arrangements that vested during the three months ended March 31, 2008 and 2009 was \$3.9 million and \$4.1 million, respectively. In such periods, \$2.0 million and \$2.1 million, respectively, of such value was reported as research and development expense, and \$1.9 million and \$2.0 million, respectively, of such value was reported as general and administrative expense.

No tax benefit was recognized related to such compensation cost during the three months ended March 31, 2008 and 2009 because we had net losses 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 three months ended March 31, 2008 and 2009.

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 EPS calculation unless they are anti-dilutive. We incurred net losses for the three months ended March 31, 2008 and 2009 and, therefore, such amounts have not been included in the calculations for those periods since they would be anti-dilutive. As a result, basic and diluted EPS are the same for each period. 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.

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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)

#### 3. Fair Value Measurements

Our available-for-sale investment portfolio consists of marketable securities, including 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 Statement of Financial Accounting Standards No. 115 ("FAS 115") "Accounting for Certain Investments in Debt and Equity Securities." The change in the fair value of these marketable securities is recorded as a component of other comprehensive income.

Marketable securities consisted of the following:

	December 31, 2008	Marcl 200	· · · · · ·
Short-term			
Corporate debt securities	\$ 63,127	\$	56,300
Total short-term			
marketable securities	63,127		56,300
Long-term			
Corporate debt securities			
and securities of			
government-sponsored			
entities	18,002		5,049
Auction rate securities	4,059		4,059
Total long-term marketable			
securities	22,061		9,108
Total marketable securities	\$ 85,188	\$	65,408

We adopted Statement of Financial Accounting Standards 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 in selling an asset or paid in transferring 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 FASB Staff Position ("FSP") No. FAS 157-2, "Effective Date of FASB Statement No. 157," we also adopted FAS 157 for our nonfinancial assets and nonfinancial liabilities on January 1, 2009 and our adoption did not have a material impact on our financial position or results of operations.

FAS 157 establishes a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed from market data obtained from sources independent of the reporting entity ("observable inputs") and the reporting entity's own assumptions about market participant assumptions developed from 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.

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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)

The following tables present our available-for-sale investments measured at fair value on a recurring basis as of December 31, 2008 and March 31, 2009, classified by the FAS 157 valuation hierarchy (discussed above):

Investment Type	D	alance at ecember 1, 2008	M I	Pair Value  Quoted  Prices in  Active  Iarkets for  Identical  Assets  (Level 1)	Sig	gnificant Other oservable Inputs Level 2)	Sig Unc	gnificant observable Inputs Level 3)
Money market funds	\$	43,859	\$	43,859	\$	-	\$	-
Corporate debt securities and securities of								
government-sponsored entities		81,129		-		81,129		-
Auction rate securities		4,059		-		-		4,059
Total	\$	129,047	\$	43,859	\$	81,129	\$	4,059
Investment Type	M	alance at Iarch 31, 2009	M I	Quoted Prices in Active Iarkets for Identical Assets (Level 1)	Sig Ob (I	gnificant Other oservable Inputs Level 2)	Sig Unc	gnificant observable Inputs Level 3)
Money market funds		larch 31,	M I	Quoted Prices in Active Iarkets for Identical Assets	Sig	2009 gnificant Other oservable Inputs	Sig Unc	gnificant observable Inputs
Money market funds Corporate debt securities and securities of	M	farch 31, 2009 55,322	M I	Quoted Prices in Active Iarkets for Identical Assets (Level 1)	Sig Ob (I	2009 gnificant Other oservable Inputs Level 2)	Sig Unc	gnificant observable Inputs
Money market funds Corporate debt securities and securities of government-sponsored entities	M	farch 31, 2009 55,322 61,349	M I	Quoted Prices in Active Iarkets for Identical Assets (Level 1)	Sig Ob (I	2009 gnificant Other oservable Inputs	Sig Unc	gnificant observable Inputs Level 3)
Money market funds Corporate debt securities and securities of	M	farch 31, 2009 55,322	M I	Quoted Prices in Active Iarkets for Identical Assets (Level 1)	Sig Ob (I	2009 gnificant Other oservable Inputs Level 2)	Sig Unc	gnificant observable Inputs

At March 31, 2009 we hold \$4.1 million (3% of total assets measured at fair value) in auction rate securities which are classified as Level 3. The fair value of these securities includes \$3.0 million of securities collateralized by student loan obligations subsidized by the U.S. government and \$1.1 million of investment company preferred stock, and do not include mortgage-backed instruments. Auction rate securities are collateralized long-term instruments that were intended to 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. We

will not realize cash in respect of the principal amount of these securities 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. As of March 31, 2009, 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.

The valuation of auction rate securities we hold is based on Level 3 unobservable inputs which consist of our internal analysis of (i) timing of expected future successful auctions, (ii) collateralization of underlying assets of the security and (iii) credit quality of the security. We re-evaluated the valuation of these securities as of March 31, 2009 and the temporary impairment amount remained unchanged at \$0.3 million, which is reflected as a part of other comprehensive loss on our accompanying condensed consolidated balance sheets. These securities are held "available-for-sale" in conformity with FAS 115 and the unrealized loss is included in other comprehensive loss. 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 accompanying condensed consolidated balance sheets.

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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 continue to monitor markets for our investments and consider the impact, if any, of market conditions on the fair market value of our investments. If market conditions for our investments do not recover, we may be required to record additional losses during the remainder of 2009. We believe we will have the ability to hold any of our investments 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 our investments are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

For those of our financial instruments with significant Level 3 inputs (all of which are auction rate securities), the following table summarizes the activities for the three months ended March 31, 2008 and 2009:

Description	For the	Significant the Three ths Ended		
Description	March 3	31, 2008	Marci	n 31, 2009
Balance at beginning of				
period	\$	-	\$	4,059
Transfers into Level 3		8,150		-
Total realized/unrealized				
gains (losses)				
Included in net loss		-		-
Included in comprehensive				
income (loss)		(408)		-
Settlements		-		-
Balance at end of period	\$	7,742	\$	4,059
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		(400)		
the reporting date	\$	(408)	\$	-

### 4. Accounts Receivable

	December 31, 2008		March 31, 2009
National Institutes of			
Health	\$	1,107	\$ 104
Royalties		229	280
		-	293

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Research and developm from collaborator	ent		
Other		1	15
Total	\$	1,337 \$	692

# 5. Accounts Payable and Accrued Expenses

	December 31,		March 31,	
		2008	2009	
Accounts payable	\$	899	\$ 712	
Accrued consulting and				
clinical trial costs		3,556	3,253	
Accrued payroll and				
related costs		1,093	1,094	
Legal and professional fees		925	1,292	
Other		23	28	
Total	\$	6,496	\$ 6,379	

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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)

### 6. Revenue Recognition

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

The Wyeth Collaboration Agreement establishes the Joint Steering Committee ("JSC") and Joint Development Committee ("JDC"), each with an equal number of representatives from both Wyeth and us. The JSC is responsible for coordinating the companies' key activities, while the JDC oversees, coordinates and expedites the development of RELISTOR by Wyeth and us. A Joint Commercialization Committee ("JCC"), composed of company representatives in number and function according to our respective responsibilities, facilitates open communication between Wyeth and us on commercialization matters.

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. During that period, the activities of the committees will be focused on Wyeth's development and commercialization obligations. Our assessment is based upon the fact that we negotiated to be on the committees as an accommodation for our granting the license for RELISTOR to Wyeth.

Under the Wyeth Collaboration Agreement, we granted to Wyeth an exclusive, worldwide license, even as to us, to develop and commercialize RELISTOR and have assigned the agreements for the manufacture of RELISTOR by third parties to Wyeth. 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 are responsible for developing the subcutaneous and intravenous formulations in the U.S. until they receive regulatory approval, while Wyeth is responsible for these formulations outside the U.S. other than Japan. Wyeth is also responsible for the development of the oral formulation worldwide excluding Japan. 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 Wyeth Collaboration Agreement, in both bulk and finished form for all products worldwide. We have no further manufacturing obligations under the Collaboration. We have transferred 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 Wyeth Collaboration Agreement.

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 is obligated to be responsible for development of such products as provided in the Wyeth Collaboration Agreement, 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 is obligated to 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 Wyeth Collaboration Agreement are to 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 Wyeth 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 March 31, 2009 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.

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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)

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 ("Substantive Milestone Method").

We are recognizing revenue in connection with the Wyeth Collaboration Agreement under the SEC's Staff Accounting Bulletin ("SAB") No. 104 ("SAB 104") "Revenue Recognition" and apply the Substantive Milestone Method. In accordance with the Emerging Issues Task Force ("EITF") Issue No. 00-21 ("EITF 00-21") "Accounting for Revenue Arrangements with Multiple Deliverables," all of our deliverables under the Wyeth 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.

Upon execution of the Collaboration Agreement, Wyeth made a non-refundable, non-creditable upfront payment of \$60.0 million, for which we deferred revenue at December 31, 2005. 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 the end of 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 Wyeth 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, which is based upon the most current budget and development plan 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 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.

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 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, consisting of: (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 a royalty period based on specified 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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## PROGENICS PHARMACEUTICALS, INC.

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

During the three months ended March 31, 2008 and 2009, we recognized \$3.2 million and \$3.2 million, respectively, of revenue from the \$60.0 million upfront payment and \$8.9 million and \$1.9 million, respectively, as reimbursement for our out-of-pocket development costs, including our labor costs. As of March 31, 2009, \$11.4 million of the \$60.0 million upfront license payment received from Wyeth, which is included in deferred revenue – current, is expected to be recognized as revenue over the period of our development obligations relating to RELISTOR, which we currently estimate will terminate at the end of 2009. In addition, at March 31, 2009, we recorded \$0.3 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 are 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 three months ended March 31, 2009, we earned royalties of \$280, based on the net sales of subcutaneous RELISTOR, and we recognized \$175 of royalty income. As of March 31, 2009, we have recorded a cumulative total of \$624 as deferred revenue – current, which is expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR, which we currently estimate will terminate at the end of 2009. We incurred \$28 of royalty costs and recognized \$18 of royalty expenses during the three months ended March 31, 2009. As of March 31, 2009, we recorded a cumulative total of \$62 of deferred royalty costs from the royalty costs incurred since we began earning royalties in the second quarter of 2008. The \$62 of deferred royalty costs are expected to be recognized as royalty expense over the period of our development obligations relating to RELISTOR.

The Wyeth Collaboration Agreement extends, unless terminated earlier, on a country-by-country and product-by-product basis, until the last to expire royalty period for any product. We may terminate the Wyeth Collaboration Agreement at any time upon 90 days written notice to Wyeth upon Wyeth's material uncured breach (30 days in the case of breach of a payment obligation). Wyeth may, with or without cause, terminate the Collaboration effective on or after the second anniversary of the first U.S. commercial sale of RELISTOR, by providing us with at least 360 days prior written notice. Wyeth may also terminate the agreement (i) upon 30 days written notice following one or more serious safety or efficacy issues that arise and (ii) upon 90 days written notice of a material uncured breach by us. Upon termination of the Wyeth Collaboration Agreement, the ownership of the license we granted to Wyeth will depend on which party initiates the termination and the reason for the termination.

We recognized the upfront payment of \$15.0 million which we received from Ono in November 2008 as research and development revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono is to own the subcutaneous filings and approvals relating to RELISTOR in Japan. In addition to the \$15.0 million upfront payment from Ono, we are entitled to receive up to an additional \$20.0 million, payable upon achievement by Ono of its development milestones. Ono is also obligated to pay to us royalties and commercialization milestones on sales by Ono of subcutaneous RELISTOR in Japan. Ono 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. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer-related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them. Revenue earned from activities we perform for Ono is recorded in research and development revenue.

# 7. 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 period. For the three months ended March 31, 2008 and 2009, we reported net losses and, therefore, potential common shares were not included since such inclusion would have been anti-dilutive.

#### PROGENICS PHARMACEUTICALS, INC.

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

In June 2008, the FASB issued FSP EITF Issue No. 03-6-1 ("FSP EITF 03-6-1") "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities." FSP EITF 03-6-1 requires entities, when calculating EPS, to allocate earnings to unvested and contingently issuable share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents when calculating EPS and also present both basic EPS and diluted EPS pursuant to the two-class method described in FASB Statement No. 128 "Earnings per Share." FSP EITF 03-6-1 is effective January 1, 2009 and requires retrospective application. We adopted FSP EITF 03-6-1 on January 1, 2009 and the adoption had no impact on basic and diluted earnings per share for the three months ended March 31, 2008 and 2009.

The calculations of net loss per share, basic and diluted, are as follows:

		Weighted Average						
		Net Loss Numerator)	Common Shares (Denominator)	Per Share Amount				
Three months ended March 31, 2008	(1	vamerator)	(Denominator)		Timount			
Basic and diluted	\$	(15,485)	29,789	\$	(0.52)			
Three months ended March 31, 2009								
Basic and diluted	\$	(1,788)	30,707	\$	(0.06)			

For the three months ended March 31, 2008 and 2009, potential common shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive include the following:

	Three Months Ended March 31,					
	2008			2009		
	Weighted			Weighted		
	Weighted	A	Average	Weighted	A	verage
	Average Exercise		Average	E	xercise	
	Number	per Price		Number	]	Price
Options and warrants	4,726	\$	18.12	4,470	\$	18.55
Restricted stock	45			29		
Total	4,771			4,499		

#### 8. 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 months ended March 31, 2008 and 2009, the components of comprehensive loss were:

Three Months	Ended March 31,
2008	2009

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Net loss	\$ (15,485)	\$ (1,788)
Change in net unrealized		
loss on marketable		
securities	386	278
Comprehensive loss	\$ (15,099)	\$ (1,510)

# 9. Commitments and Contingencies

In the ordinary course of our business, we enter into agreements with third parties, such as business partners, clinical sites and suppliers, that include indemnification provisions which, in our judgment, are normal and customary for companies in our industry sector. We generally agree to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by them 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 provisions. As a result, the estimated fair value of liabilities relating to indemnification provisions is minimal. We have no liabilities recorded for these provisions as of March 31, 2009.

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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)

10. Impact of Recently Issued Accounting Standards

In April 2009, the FASB issued three FSPs related to (i) measuring fair value when market activity declines, (ii) other-than-temporary impairments and (iii) interim fair value disclosures.

FSP No. FAS 157-4 "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly" provides additional guidance on (1) estimating fair value of an asset or liability when the volume and level of market activity for the asset or liability have significantly decreased and (2) identifying transactions that are not orderly.

FSP No. FAS 115-2 and FAS 124-2 "Recognition and Presentation of Other-Than-Temporary Impairments" changes the focus of the other-than-temporary model from an entity's ability and intent to hold a debt security until recovery. Under FSP FAS 115-2 and FAS 124-2, an other-than-temporary impairment occurs for debt securities if (1) an entity has the intent to sell the security, (2) it is more likely than not that it will be required to sell the security before recovery, or (3) it does not expect to recover the entire amortized cost basis of the security.

FSP No. FAS 107-1 and APB 28-1 "Interim Disclosures about Fair Value of Financial Instruments" expands the disclosure requirements of FASB Statement No. 107 "Disclosures about Fair Value of Financial Instruments" to interim period financial statements and requires an entity to (1) disclose the methods and significant assumptions used to estimate fair value and (2) highlight any changes of the methods and significant assumptions from prior periods.

All three FSPs are effective for interim and annual reporting periods ending after June 15, 2009. We are currently evaluating the impact these FSPs will have on our financial statements.

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

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 U.S. 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, these differences 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, including risks from market forces and trends, such as those relating to the recently-announced acquisition of our RELISTOR® collaborator, Wyeth Pharmaceuticals, by Pfizer Inc.; 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 this document and other reports filed with the U.S. Securities and Exchange Commission (SEC). In particular, we cannot assure you that 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 we assume no obligation to update any statements as a result of new information or future events or developments. 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. 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 supportive care, virology and oncology. Progenics commenced principal operations in 1988, became publicly traded in 1997 and throughout has been engaged primarily in research

and development efforts, developing manufacturing capabilities, establishing 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 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.

Supportive Care. Our first commercial product, RELISTOR® (methylnaltrexone bromide) subcutaneous injection, was approved by the U.S. Food and Drug Administration (FDA) in April 2008 for sale in the United States. Our collaboration partner, Wyeth Pharmaceuticals (Wyeth), commenced sales of RELISTOR subcutaneous injection in June, and we have begun earning royalties on world-wide sales. Regulatory approvals have also been obtained in Canada, the European Union, Australia, Venezuela and Chile. Marketing applications have been approved or are pending or scheduled in other countries, and 13 markets are expected to launch in 2009, including Spain, Italy, France, Argentina and Brazil, the largest individual markets after the U.S. In October 2008, we out-licensed to Ono Pharmaceutical Co., Ltd. (Ono), Osaka, Japan, the rights to subcutaneous RELISTOR in Japan where Wyeth elected not to develop the product. We continue development and clinical trials with respect to other indications for RELISTOR.

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In January 2009, Wyeth and Pfizer Inc. announced a definitive agreement under which Pfizer is to acquire Wyeth. We understand that the transaction is currently expected to close in late 2009 and is subject to a variety of conditions. The proposed acquisition does not trigger any change-of-control provisions in our collaboration with Wyeth, and if the acquisition is completed in the transaction structure announced by the parties, the combined Pfizer/Wyeth organization will continue to have the same rights and responsibilities under the Collaboration following the acquisition as Wyeth had before. We may not, however, learn of any plans the parties may have for RELISTOR and our Collaboration unless and until or even after the proposed transaction closes.

We and Wyeth are also developing subcutaneous RELISTOR for treatment of opioid-induced constipation (OIC) outside the advanced illness setting, in individuals with chronic pain not related to cancer, such as severe back pain that requires treatment with opioids (a phase 3 trial conducted by Wyeth), and in individuals rehabilitating from an orthopedic surgical procedure in whom opioids are used to control post-operative pain (a hypothesis generating phase 2 trial conducted by us). We are no longer enrolling patients in this latter trial and are analyzing data from the treated population. Based on positive results from the phase 3 chronic pain trial, we and Wyeth recently initiated an FDA-required one-year, open-label safety study in chronic, non-cancer pain patients and the study results found RELISTOR to be generally well tolerated. Results from this phase 3 trial and open-label safety study are intended to yield a consolidated safety database to enable filing a supplemental New Drug Application (sNDA), which is planned for submission by the end of 2010 for treatment of OIC in the chronic, non-cancer pain population.

We and Wyeth also have had in development an intravenous formulation of RELISTOR for the management of post-operative ileus (POI), a temporary impairment of the gastrointestinal tract function. Results from two phase 3 clinical trials of this formulation showed that treatment did not achieve primary or secondary end points. Recent results from a third phase 3 trial evaluating an intravenous formulation of RELISTOR in patients following abdominal hernia repair have confirmed these earlier findings.

Wyeth is leading development of an oral formulation of RELISTOR for the treatment of OIC in patients with chronic, non-cancer pain. We and Wyeth are evaluating information from optimization studies of a formulation of this product candidate to determine the next stages of development.

Development and commercialization of RELISTOR is being conducted under the Wyeth Collaboration Agreement. 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 are entitled to 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 are entitled to 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.

At inception of the Wyeth collaboration, Wyeth paid to us a \$60.0 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. 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, all subject to Wyeth's audit rights and possible reconciliation as provided in the Agreement. During the applicable royalty periods, Wyeth is obligated to pay to us royalties on the net sales of RELISTOR by Wyeth throughout the world other than Japan, where we have licensed the rights to subcutaneous RELISTOR to Ono.

We recognize 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 recognize revenue for a portion of the \$60.0 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.

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Under our License Agreement with Ono, in November 2008 we received from Ono an upfront payment of \$15.0 million, and are entitled to receive potential milestones, upon achievement of development responsibilities by Ono, of up to \$20.0 million, 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, Japanese pharmaceutical regulatory authorities 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. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them.

Because Wyeth is not developing RELISTOR in Japan, we will not receive from it Japan-related milestone payments provided in the original Wyeth Collaboration Agreement. 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). As a result, we now have the potential to receive a total of \$334.0 million in development and commercialization milestone payments from Wyeth under the Wyeth Collaboration (of which \$60.0 million relate to the intravenous formulation of RELISTOR), and of which \$39.0 million (\$5.0 million relating to the intravenous formulation) have been paid to date.

Virology. In the area of virology, we are developing two viral-entry inhibitors: a humanized monoclonal antibody, PRO 140, for treatment of human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), and a proprietary orally-available small-molecule drug candidate, PRO 206, for treatment of hepatitis C virus infection (HCV). Based on results from previous phase 2 clinical trials, we are developing the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for convenient, weekly self-administration, and we are conducting preclinical development activities in preparation for filing an Investigational New Drug (IND) application for PRO 206. We are also engaged in research regarding a prophylactic vaccine against HIV infection.

Oncology. In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal antibody-drug conjugate (ADC) directed against prostate specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. 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 (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.

Results of Operations (dollars in thousands)

#### Revenues:

Our sources of revenue during the three months ended March 31, 2008 and 2009 included our Collaboration with Wyeth, our License Agreement with Ono, our research grants and contract from the National Institutes of Health (NIH) and, to a small extent, our sale of research reagents. In June 2008, we began recognizing royalty income from net sales by Wyeth of subcutaneous RELISTOR.

Three Months Ended March 31,

Sources of Revenue	2008	2009	Percent Change
Research and development	\$ 12,110	\$ 20,144	66%
Royalty income	_	175	N/A
Research grants and contract	2,613	507	(81%)
Other revenues	39	78	100%
Total	\$ 14,762	\$ 20,904	42%

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Research and development revenue:

• Wyeth Collaboration. During the three months ended March 31, 2008 and 2009, we recognized \$12,110 and \$5,097, respectively, of revenue from Wyeth, consisting of \$3,234 and \$3,182, respectively, from amortization of the \$60,000 upfront payment we received upon entering into our Collaboration in December 2005, and \$8,876 and \$1,915, respectively, as reimbursement for our development expenses.

From the inception of the Wyeth Collaboration through March 31, 2009, we recognized \$48,619 of revenue from the \$60,000 upfront payment, \$101,233 as reimbursement for our development expenses, and a total of \$39,000 for non-refundable milestone payments. We expect reimbursement revenue to decline during the remainder of 2009 compared to 2008, as research and development for RELISTOR decreases.

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 thru March 31, 2009. We expect revenue from amortization of the remaining \$11.4 million of unamortized upfront premium to increase during the remainder of 2009 compared to 2008, and that the amortization will be completed by the end of 2009.

• Ono License Agreement. In October 2008, we entered into a License Agreement with Ono and in November 2008, received an upfront payment of \$15.0 million. We are entitled to receive potential milestones and royalty payments. During the three months ended March 31, 2009, we recognized the upfront payment as revenue, upon satisfaction of our performance obligations and recorded \$47 of reimbursement revenue for activities requested by Ono.

Royalty income. We began earning royalties from net sales by Wyeth of subcutaneous RELISTOR in June 2008. During the three months ended March 31, 2009, we earned royalties of \$280, based on net sales of RELISTOR and recognized \$175 of royalty income. As of March 31, 2009, we have recorded a cumulative total of \$624 as deferred revenue – current. The \$624 of deferred royalty revenue is expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR, which we currently estimate will terminate at the end of 2009. Our royalties from net sales by Wyeth of RELISTOR, as defined, are based on specified royalty rates ranging 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.

Global net sales of RELISTOR, which began last June, were \$1.9 million for the first quarter of 2009, an increase of 23% compared to \$1.5 million in the fourth quarter of 2008. This quarterly increase includes a 42% increase in U.S. RELISTOR sales from \$0.8 million in the prior year's fourth quarter to \$1.2 million in the first quarter of 2009. Non-U.S. RELISTOR sales totaled \$0.7 million in the first quarter of 2009, unchanged from the prior quarter. The number of U.S. institutions ordering RELISTOR in the first quarter of 2009 grew by approximately 27% over the fourth quarter of 2008 as formulary approvals continue to increase.

Research grants and contract. In 2003, we were awarded a contract by the NIH (NIH Contract) 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 provided for pre-clinical research, development and early clinical testing. These funds were 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 amounted to \$15,509. Funding under this contract included the payment of an aggregate of \$1,617 in fees, subject to achievement

of specified milestones. Through December 31, 2008, we had recognized revenue of \$15,509 from this contract, including \$180 for the achievement of two milestones. We were informed by the NIH that it has decided to fund the NIH Contract only through December 2008. We have applied for additional awards for this program and are currently funding it with our own resources pending a decision on that application.

Revenues from research grants and contract from the NIH decreased from \$2,613 for the three months ended March 31, 2008 to \$507 for the three months ended March 31, 2009; \$2,093 and \$507 from grants and \$520 and zero from the NIH Contract for the three months ended March 31, 2008 and 2009, respectively. The decrease in grant and contract revenue resulted from fewer active grants and reimbursable expenses in 2009 than in 2008, and the expiration of the NIH Contract in December 2008.

Other revenues, primarily from orders for research reagents, increased from \$39 for the three months ended March 31, 2008 to \$78 for the three months ended March 31, 2009.

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#### 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, including license fees and royalty expense, decreased from \$23,939 for the three months ended March 31, 2008 to \$15,478 for the three months ended March 31, 2009, as follows:

	Three Months Ended March 31,		
	2008	2009	Percent Change
Salaries and benefits (cash)	\$6,559	\$6,115	(7%)

Salaries and benefits (cash) decreased due to a decline in average headcount from 200 to 190 for the three months ended March 31, 2008 and 2009, respectively, in the research and development, manufacturing and clinical departments due to transfers of information technology personnel from the research and development to general and administrative departments.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Share-based compensation (non-cash)	\$2,012	\$2,106	5%

Share-based compensation (non-cash) increased due to higher compensation expenses from the vesting of additional share-based compensation awards partially offset by a decrease in employee stock purchase plan expenses for the three months ended March 31, 2009 compared to the three months ended March 31, 2008. See Critical Accounting Policies – Share-Based Payment Arrangements.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Clinical trial costs	\$4,863	\$975	(80%)

Clinical trial costs decreased primarily due to lower expenses for (i) RELISTOR (\$3,325), from reduced clinical trial activities, (ii) HIV (\$494), due to decreased PRO 140 clinical trial activities, and (iii) Cancer (\$69), all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Laboratory supplies	\$1,182	\$889	(25%)

Laboratory supplies decreased due to lower expenses for (i) HIV (\$553), from a decline in the purchases of drug supplies, and (ii) Other projects (\$83), partially offset by an increase in Cancer (\$345), due to higher expenses for PSMA, all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Contract manufacturing and subcontractors	\$4,646	\$2,629	(43%)

Contract manufacturing and subcontractors decreased due to lower (i) HIV expenses (\$2,099), from a decline in manufacturing expenses for PRO 140 and (ii) RELISTOR expenses (\$724), partially offset by increases in both Cancer (\$420), due to higher contract manufacturing expenses for PSMA, and Other (\$386), all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008. 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.

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	Three Mont March		
	2008	2009	Percent Change
Consultants	\$1,635	\$318	(81%)

Consultants expenses decreased due to lower expenses for (i) RELISTOR (\$877), (ii) Cancer (\$273) and (iii) Other projects (\$163), all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008. These expenses are related to the monitoring of clinical trials as well as the analysis of data from completed clinical trials and vary as the timing and level of such services are required.

		Three Months Ended March 31,	
	2008	2009	Percent Change
License fees	\$1,149	\$630	(45%)

License fees decreased primarily due to a decline in HIV expenses (\$779), partially offset by an increase in Cancer (\$250), all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Royalty expense	\$ -	\$18	N/A

We incurred \$28 of royalty costs and recognized \$18 of royalty expenses during the three months ended March 31, 2009. As of March 31, 2009, we recorded a cumulative total of \$62 of deferred royalty charges from the royalty costs incurred since we began earning royalties in the second quarter of 2008. The \$62 of deferred royalty charges are expected to be recognized as royalty expense over the period of our development obligations relating to RELISTOR, which we currently estimate will terminate at the end of 2009.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Other operating expenses	\$1,893	\$1,798	(5%)

Other operating expenses decreased for the three months ended March 31, 2009 compared to the three months ended March 31, 2008, primarily due to a decline in computer expenses (\$61), facilities (\$43), insurance (\$30), travel (\$14) and other operating expenses (\$47), partially offset by an increase in rent (\$100).

General and Administrative Expenses decreased from \$7,152 for the three months ended March 31, 2008 to \$6,801 for the three months ended March 31, 2009, as follows:

Three Months Ended
March 31,
Percent
2008 2009 Change

Salaries and benefits (cash) \$2,258 \$2,171 (4%)

Salaries and benefits (cash) decreased due to lower bonus expenses partially offset by higher salaries expenses resulting from an increase in average headcount, from 50 to 52 in the general and administrative departments for the three months ended March 31, 2008 and 2009, respectively, due to transfers of information technology personnel from the research and development to general and administrative departments.

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	Three Months Ended March 31,		
	2008	2009	Percent Change
Share-based compensation (non-cash)	\$1,900	\$2,036	7%

Share-based compensation (non-cash) increased due to higher compensation expenses from the vesting of additional share-based compensation awards partially offset by a decrease in employee stock purchase plan expenses for the three months ended March 31, 2009 compared to the three months ended March 31, 2008. See Critical Accounting Policies –Share-Based Payment Arrangements.

	Three Months Ended March 31,		
	2008	2009	Percent Change
Consulting and professional fees	\$1,707	\$1,453	(15%)

Consulting and professional fees decreased due to a decline in patent fees (\$425), consultants (\$114) and other miscellaneous costs (\$20), which were partially offset by an increase in legal fees (\$268) and audit and tax fees (\$37), all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008.

	Three Mon	ths Ended	
	Marc	h 31,	
	2008	2009	Percent Change
Other operating expenses	\$1,287	\$1,141	(11%)

Other operating expenses decreased due to lower spending on recruiting (\$130), conferences and seminars (\$29) and other operating expenses (\$67), partially offset by increases in rent (\$39), taxes (\$26) and investor relations (\$17), all for the three months ended March 31, 2009 compared to the three months ended March 31, 2008.

		Three Months Ended March 31,				
	2008	2009	Percent Change			
Depreciation and amortization	\$1,114	\$1,203	8%			

Depreciation and amortization expense increased from \$1,114 for the three months ended March 31, 2008 to \$1,203 for the three months ended March 31, 2009, due to fixed asset purchases in 2008.

	Three Mont March				
	2008	2009	Percent Change		
Interest income	\$1,958	\$790	(60%)		

Interest income decreased from \$1,958 for the three months ended March 31, 2008 to \$790 for the three months ended March 31, 2009. 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 March 31, 2008 and 2009, investment income decreased from \$2,053 to \$1,089, respectively, due to a decrease in interest rates and lower average balance of cash equivalents and marketable securities in 2009 than in 2008. Amortization of premiums, net of discounts, was (\$95) and (\$299) for the three months ended March 31, 2008 and 2009, respectively.

#### **Income Taxes:**

For the three months ended March 31, 2008 and 2009, we had losses both for book and tax purposes.

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Net Loss:

Our net loss was \$15,485 for the three months ended March 31, 2008 compared to \$1,788 for the same period of 2009.

### Liquidity and Capital Resources

We have to date generated only modest amounts of product and royalty revenue, and consequently have relied principally on external funding and our Collaboration with Wyeth to finance our operations. We have funded our operations since inception primarily through private placements of equity securities, payments received under collaboration agreements, public offerings of common stock, funding under government research grants and contracts, interest on investments, proceeds from the exercise of outstanding options and warrants, sale of our common stock under our two employee stock purchase plans (Purchase Plans) and a license agreement. We are currently in discussions with government agencies and others to obtain pivotal clinical trial funding to support our PRO 140 compound, and are pursuing strategic collaborations with biopharmaceutical companies to support our development plan for PSMA ADC.

At March 31, 2009, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$127.7 million compared with \$141.4 million at December 31, 2008. We expect that our existing cash, cash equivalents and marketable securities at March 31, 2009 are sufficient to fund current operations beyond one year. Our cash flow from operating activities was negative for the three months ended March 31, 2008 and 2009 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 Collaboration with Wyeth provided us with a \$60.0 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 the end of 2009. For the three months ended March 31, 2008 and 2009, we recorded \$8.9 million and \$1.9 million, respectively, of such reimbursement. Wyeth is obligated to make up to \$295.0 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 are entitled to receive royalty payments from Wyeth as the product is sold in the various countries (other than Japan) where marketing approval has been obtained. We are also entitled to receive royalty payments upon the sale of all other products developed under the Wyeth Collaboration Agreement.

Under our License Agreement with Ono, we received from Ono, in November 2008, an upfront payment of \$15.0 million, which was recognized as revenue during the first quarter of 2009, upon satisfaction of our performance obligations, and are entitled to receive potential milestone payments, upon achievement of development responsibilities by Ono, of up to \$20.0 million, commercial milestones and royalties on sales of subcutaneous RELISTOR in Japan. Ono is also responsible for development and commercialization costs for subcutaneous RELISTOR in Japan.

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 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 were 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 was \$15.5 million. Funding under this contract included the payment of an aggregate of \$1.6 million in fees, subject to achievement of specified milestones. Through December 31, 2008, we had recognized revenue of \$15.5 million from this contract, including \$0.2 million for the achievement of two milestones. We were informed by the NIH that it has decided to fund this contract only through December 2008. We have applied for additional awards for this program and are currently funding it with our own resources pending a decision on that application.

A substantial portion of our revenues to date has been derived from federal government grants. During the three months ended March 31, 2008 and 2009, we recognized as revenue awards made to us by the NIH between 2004 and 2008, to partially fund some of our programs. For the three months ended March 31, 2008 and 2009, we recognized \$2.1 million and \$0.5 million, respectively, of revenue from all of our NIH grants.

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Changes in Accounts receivable and Accounts payable for the three months ended March 31, 2008 and 2009 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, 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.

A substantial portion of our cash and cash equivalents are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee programs. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale and are predominantly not guaranteed. These investments, while rated investment grade by the Standard & Poor's and Moody's rating agencies and predominantly having scheduled maturities in 2009, are heavily concentrated in the U.S. financial sector, which continues to be under extreme stress.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at March 31, 2009, we continue to hold approximately \$4.1 million of auction rate securities which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. To date, we have received all scheduled interest payments on these securities. We will not realize cash in respect of the principal amount of these securities 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 monitor markets for our investments, but cannot guarantee that additional losses will not be required to be recorded. Valuation of securities 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, ongoing strength and quality of market credit and liquidity and general economic and market conditions. We do not believe the carrying values of our investments are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

Our marketable securities are purchased and, in the case of auction rate securities, sold by third-party brokers in accordance with our investment policy guidelines. Our brokerage account requires that all marketable securities be held to maturity unless authorization is obtained from us to sell earlier. In fact, we have a history of holding all marketable securities to maturity. We, therefore, believe that we have the intent and ability to hold any securities with unrealized losses until a recovery of fair value (which may be maturity), and we do not consider these marketable securities to be other than temporarily impaired at March 31, 2009.

Financing Activities. During the three months ended March 31, 2008 and 2009, we received cash of \$1.5 million and \$1.5 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants and from the sale of our common stock under our Purchase Plans. 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.

In the prior year, we obtained approvals from the FDA, as well as European Union, Canadian, Australian, Venezuelan and other regulatory authorities, for our first commercial product, RELISTOR. We continue development and clinical trials with respect to RELISTOR and our other product candidates. Unless we obtain regulatory approval from the FDA for additional product candidates and/or enter into agreements with corporate collaborators with respect to the development of our technologies in addition to that for RELISTOR, we will be required to fund our operations for periods in the future, by seeking additional financing through future offerings of equity or debt securities, through collaborative, license or royalty financing agreements, or funding from additional grants and government contracts. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us may seriously jeopardize the future success of our business.

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#### Uses of Cash

Operating Activities. The majority of our cash has been used to advance our research and development programs. We currently have major research and development programs investigating supportive care, virology and oncology, and are conducting several smaller research projects in the areas of virology and oncology. Our total expenses for research and development from inception through March 31, 2009 have been approximately \$494.0 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 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 may be subject to further revision, are \$6.0 million, over the period from April 1, 2009 to December 31, 2009.

For the three months ended March 31, 2008 and 2009, research and development costs incurred by project were as follows:

	Th	Three Months Ended March						
		31,						
		2008	2	2009				
RELISTOR	\$	9.3	\$	2.4				
HIV		9.7		4.4				
Cancer		2.5		5.6				
Other programs		2.5		3.1				
Total	\$	24.0	\$	15.5				

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 are funded by Wyeth in the U.S. and outside the U.S. except for Japan, where development, manufacturing and commercialization expenses are required to 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 our cash payments that would have been due to those licensors in the future upon the achievement of certain events, including sales of RELISTOR products. We are, however, making royalty payments and are responsible for making other payments to the University of Chicago upon the occurrence of certain events.

Investing Activities. During the three months ended March 31, 2008 and 2009, we spent \$0.8 million and \$0.6 million, respectively, on capital expenditures. Those expenditures have been primarily related to the purchase of additional laboratory equipment for our ongoing and future research and development projects.

# **Contractual Obligations**

Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of March 31, 2009 for future payments under these agreements:

	Payments due by March 31,								
	Total		2010	2	011-2012	2	2013-2014	Th	ereafter
				(in	millions)				
Operating leases	\$ 4.2	\$	2.5	\$	1.0	\$	0.5	\$	0.2
License and collaboration agreements (1)	82.3		1.8		4.7		13.0		62.8
Total	\$ 86.5	\$	4.3	\$	5.7	\$	13.5	\$	63.0

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

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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.

### **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, 2008. 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 SEC's Staff Accounting Bulletin (SAB) No. 104 (SAB 104), Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21) "Accounting for Revenue Arrangements with Multiple Deliverables" and EITF Issue No. 99-19 (EITF 99-19) "Reporting Revenue Gross as a Principal Versus Net as an Agent." Our license and co-development agreement with Wyeth includes a non-refundable upfront license fee, reimbursement of development costs, research and development payments based upon our achievement of clinical development milestones, contingent payments based upon the achievement by Wyeth of defined events and royalties on product sales. We began recognizing research revenue from Wyeth on

January 1, 2006. During the three months ended March 31, 2008 and 2009, we also recognized revenue from government research grants (and contract in the 2008 period), which are used to subsidize a portion of certain of our research projects (Projects), exclusively from the NIH. We also recognized revenue from the sale of research reagents during those periods.

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

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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 Wyeth Collaboration based upon the most current budget approved by both Wyeth and us. Such performance obligations are provided by us on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. Since we have no obligation to develop the subcutaneous and intravenous formulations of RELISTOR outside the U.S. or the oral formulation at all and have no significant commercialization obligations for any product, recognition of revenue for the upfront payment is not required during those periods, if they extend beyond the period of our development obligations.

During the course of a collaboration agreement, e.g., the Wyeth Collaboration, 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, 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. 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 Wyeth Collaboration, we have assessed the nature of our involvement with the Joint Steering Committee, Joint Development Committee and Joint Commercialization Committee. 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 is required to continue to develop the oral formulation and to commercialize all formulations as provided in the Wyeth Collaboration, 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 – Supportive Care, 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.

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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 (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 Wyeth Collaboration; 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 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 Wyeth Collaboration 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 to the achievement of those milestones. Therefore, we recognized the milestone payments as revenue in the respective periods in which the milestones were earned.

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

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

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

Royalty revenue is recognized 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 condensed 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 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.

We recognized the upfront payment of \$15.0 million, which we received from Ono in November 2008, as research and development revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono is to own the subcutaneous filings and approvals relating to RELISTOR in Japan. In addition to the \$15.0 million upfront payment from Ono, we are entitled to receive up to an additional \$20.0 million, payable upon achievement by Ono of its development milestones. Ono is also obligated to pay to us royalties and commercialization milestones on sales by Ono of subcutaneous RELISTOR in Japan. Ono 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. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer-related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them. Revenue earned from activities we perform for Ono is recorded in research and development revenue.

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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 and shares issued under our Purchase Plans, which are compensatory under Statement of Financial Accounting Standards No. 123 (revised 2004) (FAS 123(R)) "Share-Based Payment." We account for share-based compensation to non-employees, including non-qualified stock options and restricted stock, in accordance with EITF 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."

Compensation cost for all share-based awards 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. As of March 31, 2009, there was \$13.3 million, \$7.5 million and \$0.1 million of total unrecognized compensation cost related to non-vested stock options under the plans, the non-vested shares and the Purchase Plans, respectively. Those costs are expected to be recognized over weighted average periods of 2.5 years, 1.6 years and 0.04 years, respectively. We apply a forfeiture rate to the number of unvested awards in each reporting period in order to estimate the number of awards that are expected to vest. Estimated forfeiture rates are based upon historical data on vesting behavior of employees. We adjust the total amount of compensation cost recognized for each award, in the period in which each award vests, to reflect the actual forfeitures related to that award. Changes in our estimated forfeiture rate will result in changes in the rate at which compensation cost for an award is recognized over its vesting period. We have made an accounting policy decision to use the straight-line method of attribution of compensation expense, under which the grant date fair value of share-based awards will be recognized on a straight-line basis over the total requisite service period for the total award.

Under FAS 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 three months ended March 31, 2008 and 2009, the volatility of our common stock has been high, 66%-90% and 71%-91%, respectively, which is common for entities in the biotechnology industry that do not have commercial products. A higher volatility input to the Black-Scholes model increases the resulting compensation expense.
- The expected term of options granted represents the period of time that options granted are expected to be outstanding. For the three months ended March 31, 2008 and 2009, our expected term was calculated based upon historical data related to exercise and post-termination cancellation activity. Accordingly, for grants made to

employees and officers (excluding our Chief Executive Officer) and directors, we are using expected terms of 5.33 and 8.0 years and 5.3 and 7.3 years, respectively. Beginning in the third quarter of 2008, we began estimating the expected term of stock options granted to our Chief Executive Officer separately from stock options granted to employees and officers, and the expected term was 7.8 years in the first quarter of 2009. Expected term for options granted to non-employee consultants was ten years, which is the contractual term of those options. 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).

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- 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, 2002, 2003, 2004 and 2005, on July 3, 2006 and on July 2, 2007 cliff vests after nine years and eleven months from the respective grant date. The July 1, 2002, 2003 and 2005 awards have 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 FAS 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 Chief Executive Officer which vest on the basis of the achievement of specified performance or market-based milestones. The options have an exercise price equal to the closing price on our common stock on the date of grant while the restricted stock awards do not include an exercise price. The awards to our Chief Executive Officer are valued using a Monte Carlo simulation and the expense related to these grants will be recognized over the shortest estimated time for the achievement of the performance or market conditions. The awards will not vest unless one of the milestones is achieved or the market condition is met. 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.

The fair value of shares purchased under the Purchase Plans is estimated on the date of grant in accordance with Financial Accounting Standards Board (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 net losses for the three months ended March 31, 2008 and 2009, and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for those periods. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculations, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

For the three months ended March 31, 2008 and 2009, no tax benefit was recognized related to total compensation cost for share-based payment arrangements recognized in operations because we had net losses for 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 three months ended March 31, 2008 and 2009.

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 as incurred, and are 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, mitigates 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.

Fair Value Measurements. Our available-for-sale investment portfolio consists of money market funds, 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 Statement of Financial Accounting Standards 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.

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We adopted Statement of Financial Accounting Standards 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 in selling an asset or paid in transferring the 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 FASB Staff Position (FSP) No. FAS 157-2, "Effective Date of FASB Statement No. 157," we also adopted FAS 157 for our nonfinancial assets and nonfinancial liabilities on January 1, 2009 and our adoption did not have a material impact on our financial position or results of operations.

FAS 157 establishes a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed from market data obtained from sources independent of the reporting entity ("observable inputs") and the reporting entity's own assumptions about market participant assumptions developed from 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 April 2009, the FASB issued three FSPs related to (i) measuring fair value when market activity declines, (ii) other-than-temporary impairments and (iii) interim fair value disclosures.

FSP No. FAS 157-4 "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly" provides additional guidance on (1) estimating fair value of an asset or liability when the volume and level of market activity for the asset or liability have significantly decreased and (2) identifying transactions that are not orderly.

FSP No. FAS 115-2 and FAS 124-2 "Recognition and Presentation of Other-Than-Temporary Impairments" changes the focus of the other-than-temporary model from an entity's ability and intent to hold a debt security until recovery. Under FSP FAS 115-2 and FAS 124-2, an other-than-temporary impairment occurs for debt securities if (1) an entity has the intent to sell the security, (2) it is more likely than not that it will be required to sell the security before recovery, or (3) it does not expect to recover the entire amortized cost basis of the security.

FSP No. FAS 107-1 and APB 28-1 "Interim Disclosures about Fair Value of Financial Instruments" expands the disclosure requirements of FASB Statement No. 107 "Disclosures about Fair Value of Financial Instruments" to interim period financial statements and requires an entity to (1) disclose the methods and significant assumptions used to estimate fair value and (2) highlight any changes of the methods and significant assumptions from prior periods.

All three FSPs are effective for interim and annual reporting periods ending after June 15, 2009. We are currently evaluating the impact these FSPs will have on our financial statements.

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 money market funds, taxable corporate debt securities, securities of government-sponsored entities and auction rate securities. Our investments totaled \$120.7 million at March 31, 2009. Approximately \$61.3 million of these investments had fixed interest rates, and \$59.4 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 March 31, 2009 market interest rates would result in a decrease of approximately \$0.02 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 March 31, 2009, we continue to hold approximately \$4.1 million (3% 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 the impact, if any, of market conditions 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 losses during the remainder of 2009, 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, ongoing strength and quality of market credit and liquidity and general economic and market conditions. We do not believe the carrying values of these auction rate securities are other than temporarily 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. We re-evaluated the valuation of these securities as of March 31, 2009 and the temporary impairment amount remained unchanged at \$0.3 million. A 100 basis point increase to our internal analysis would result in an increase of approximately \$0.042 million in the temporary impairment of these securities as of the three months ended March 31, 2009.

#### 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 at the reasonable assurance level.

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, 2008 and our other public reports. In addition, the following risk factors have changed during the quarter ended March 31, 2009:

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

We have incurred substantial losses since our inception. As of March 31, 2009, we had an accumulated deficit of \$300.5 million. We have derived no significant revenues from product sales or royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur additional operating losses in the future, which could increase significantly as we expand our clinical trial programs and other product development efforts.

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

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

As of March 31, 2009, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$127.7 million. During the three months ended March 31, 2009, we had a net loss of \$1.8 million and cash used in operating activities was \$14.5 million.

Although our spending on RELISTOR has been significant during 2007, 2008 and through the first quarter of 2009, our net expenses for RELISTOR have been reimbursed by Wyeth under the Collaboration Agreement. We expect our spending on RELISTOR will decline during the remainder of 2009 and thereafter, which will result in less reimbursement by Wyeth.

With regard to other product candidates, we expect to continue to incur significant development expenditures, and do not have committed external sources of funding for most of these projects. These expenditures will be funded from cash on hand, or we may seek additional external funding for them, most likely through collaborative, license or royalty financing agreements with one or more pharmaceutical companies, securities issuances or government grants or contracts. We cannot predict when we will need additional funds, how much we will need or if additional funds will be available, especially in light of current conditions in global credit and financial markets. Our need for future funding will depend on numerous factors, such as the availability of new product development projects or other opportunities which we cannot predict, and many of which are outside our control. In particular, we cannot assure you that any currently-contemplated or future initiatives for funding our product candidate programs will be successful.

Our access to capital funding is always uncertain. Recent turmoil in the international capital markets has exacerbated this uncertainty. 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 would seriously 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 existing stockholders. If we raise funds by selling equity securities, current stockholders will be diluted, and new investors could have rights

superior to existing stockholders. Raising funds by selling debt securities often entails significant restrictive covenants and repayment obligations.

A substantial portion of our cash and cash equivalents are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee programs. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale and are predominantly not guaranteed. These investments, while rated investment grade by the Standard & Poor's and Moody's rating agencies and predominantly having scheduled maturities in 2009, are heavily concentrated in the U.S. financial sector, which continues to be under extreme stress.

At March 31, 2009, we continue to hold approximately \$4.1 million of auction rate securities which, in the event of auction failure, have been reset according to the contractual terms in the governing instruments. To date, we have received all scheduled interest payments on these securities. We will not realize cash in respect of the principal amount of these securities 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.

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We monitor markets for our investments, but cannot guarantee that additional losses will not be required to be recorded. Valuation of securities 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, ongoing strength and quality of market credit and liquidity and general economic and market conditions.

Competing products may adversely affect our products.

We are aware that Adolor Corporation, in collaboration with GlaxoSmithKline, 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." 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, and that Nektar Therapeutics has completed a phase 2 study of an oral once-a-day peripheral opioid antagonist in patients with OIC. In Europe, we are aware that Mundipharma International markets TARGIN® (oxycodone/naloxone, a combination of an opioid and systemic opioid antagonist). Any of these drugs may achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of these competitors may impair our ability to compete effectively in the market.

In the case of PRO 140, five classes of products have been approved for marketing by the FDA for the treatment of HIV infection and AIDS. These drugs have shown efficacy in reducing the concentration of HIV in the blood and prolonging asymptomatic periods in HIV-positive individuals. All have been required to show efficacy in conjunction with other agents, which we have not demonstrated for PRO 140. We are aware of two approved drugs designed to treat HIV infection by blocking viral entry (Trimeris' FUZEON® and Pfizer's SELZENTRY<sup>TM</sup>). We are also aware of various HCV drugs in pre-clinical or clinical development.

Radiation and surgery are two principal traditional forms of treatment for prostate cancer, to which our PSMA-based development efforts are directed. If the disease spreads, hormone (androgen) suppression therapy is often used to slow the cancer's progression. This form of treatment, however, can eventually become ineffective. We are aware of several competitors who are developing alternative treatments for castrate-resistant prostate cancer, some of which are directed against PSMA.

If we are unable to negotiate collaborative agreements, our cash burn rate could increase and our rate of product development could decrease.

Our business strategy includes entering into collaborations with pharmaceutical and biotechnology companies to develop and commercialize product candidates and technologies. We may not be successful in negotiating additional collaborative arrangements. If we do not enter into new collaborative arrangements, we would have to devote more of our resources to clinical product development and product-launch activities, seeking additional sources of capital, and our cash burn rate would increase or we would need to take steps to reduce our rate of product development. In particular, we cannot assure you that any currently-contemplated or future collaboration or other initiatives for funding our product candidate programs will be successfully concluded.

A substantial portion of our funding comes from federal government grants and research contracts. We cannot rely on these grants or contracts as a continuing source of funds.

A substantial portion of our revenues to date, albeit decreasing in 2007 and 2008, has been derived from federal government grants and research contracts. During the years ended December 31, 2006, 2007 and 2008, we generated

revenues from awards made to us by the NIH between 2003 and 2008, to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them due to their own budgetary constraints. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing grants or contracts may be less than those received to date. Therefore, we will need to provide funding on our own or obtain other funding. In particular, we cannot assure you that any currently-contemplated or future efforts to obtain funding for our product candidate programs through government grants or contracts will be successful, or that any such arrangements which we do conclude will supply us with sufficient funds to complete our development programs without providing additional funding on our own or obtaining other funding.

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, 2007 and March 31, 2009, our stock price has ranged from \$4.33 to \$30.31 per share. Between April 1, 2009 and May 6, 2009, it has ranged from \$5.03 to \$7.05 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 relationships with Wyeth, Pfizer (if its acquisition of Wyeth is completed) and Ono 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;

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- developments in patent or other proprietary rights;
  - governmental regulation;
- changes in reimbursement policies or health care legislation;
- public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
  - our ability to fund on-going operations;
  - fluctuations in our operating results; and
    - general market conditions.

Purchases of our common shares pursuant to our 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 discontinued, our stock price may fall.

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

At March 31, 2009, our directors and executive officers and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately one-fifth of our outstanding shares of common stock. At that date, our five largest stockholders, excluding our directors and executive officers and stockholders affiliated with Tudor, beneficially own or control in the aggregate approximately 57% of our outstanding shares. Our directors and executive officers and Tudor-related stockholders, should they choose to act together, could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could have the effect of delaying or preventing a change in control of us and, consequently, could adversely affect the market price of our common stock. Other significant but unrelated stockholders could also exert influence in such matters.

If there are substantial sales of our common stock, the market price of our common stock could decline.

Sales of substantial numbers of shares of common stock could cause a decline in the market price of our stock. We require substantial external funding to finance our research and development programs and may seek such funding through the issuance and sale of our common stock. In addition, some of our other stockholders are entitled to require us to register their shares of common stock for offer or sale to the public. We have filed Form S-8 registration statements registering shares issuable pursuant to our equity compensation plans and periodically seek to increase the amount of securities available under these plans. Any sales by existing stockholders or holders of options, or other rights, may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common stock.

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

We did not repurchase any common shares during the three months ended March 31, 2009 (see Note 1 - Corporate - Related Matters to our financial statements).

Item 6. Exhibits

**Exhibits** 

(a)

#### Exhibit

# **Number Description**

- 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

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Date: May 11, 2009

#### **SIGNATURES**

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

PROGENICS PHARMACEUTICALS, INC.

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)