

PROGENICS PHARMACEUTICALS INC

Form 10-Q

November 08, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

Or

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

For the transition period from _____ to _____

Commission File No. 000-23143

PROGENICS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

13-3379479
(I.R.S. Employer Identification 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 ☒ No ☐

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

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to submit and post such files). Yes ☐ No ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting

company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 3, 2010 there were 33,038,743 shares of common stock, par value \$.0013 per share, of the registrant outstanding.

PROGENICS PHARMACEUTICALS, INC.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS(amounts in thousands, except for par value and share amounts)
(Unaudited)

	September 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$58,394	\$90,903
Marketable securities	-	1,501
Accounts receivable	4,477	7,522
Other current assets	1,926	1,468
Total current assets	64,797	101,394
Marketable securities	3,608	3,792
Fixed assets, at cost, net of accumulated depreciation and amortization	6,404	6,560
Other assets	1,137	1,867
Total assets	\$75,946	\$113,613
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$6,648	\$5,836
Other current liabilities	107	170
Total current liabilities	6,755	6,006
Other liabilities	1,781	-
Total liabilities	8,536	6,006
Commitments and contingencies (Note 7)		
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 – 33,105,142 in 2010 and 32,142,062 in 2009	43	42
Additional paid-in capital	450,655	439,943
Accumulated deficit	(380,255)	(329,330)
Accumulated other comprehensive loss	(292)	(307)
Treasury stock, at cost (200,000 shares in 2010 and 2009)	(2,741)	(2,741)
Total stockholders' equity	67,410	107,607
Total liabilities and stockholders' equity	\$75,946	\$113,613

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Research and development	\$82	\$4,431	\$1,175	\$29,206
Royalty income	620	509	1,826	976
Research grants	1,234	404	2,667	1,421
Other revenues	31	75	127	189
Total revenues	1,967	5,419	5,795	31,792
Expenses:				
Research and development	12,967	11,318	35,518	39,009
License fees – research and development	110	136	1,217	961
General and administrative	5,414	5,844	17,568	19,758
Royalty expense	62	51	182	98
Depreciation and amortization	532	1,207	2,283	3,633
Total expenses	19,085	18,556	56,768	63,459
Operating loss	(17,118)	(13,137)	(50,973)	(31,667)
Other income:				
Interest income	17	123	48	1,457
Gain on sale of marketable securities	-	-	-	237
Total other income	17	123	48	1,694
Net loss	\$(17,101)	\$(13,014)	\$(50,925)	\$(29,973)
Net loss per share - basic and diluted	\$(0.52)	\$(0.41)	\$(1.57)	\$(0.97)
Weighted-average shares - basic and diluted	32,814	31,428	32,444	31,060

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

(amounts in thousands)
(Unaudited)

	Common Stock		Additional		Accumulated Other Comprehensive (Loss) Income		Treasury Stock		Total
	Shares	Amount	Paid-In Capital	Accumulated Deficit			Shares	Amount	
Balance at December 31, 2009	32,142	\$42	\$ 439,943	\$ (329,330)	\$ (307)		(200)	\$(2,741)	\$107,607
Comprehensive loss:									
Net loss	-	-	-	(50,925)	-		-	-	(50,925)
Net change in unrealized loss on marketable securities	-	-	-	-	15		-	-	15
Total comprehensive loss									(50,910)
Compensation expenses for share-based payment arrangements	-	-	7,726	-	-		-	-	7,726
Issuance of restricted stock, net of forfeitures	187	-	-	-	-		-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	776	1	2,986	-	-		-	-	2,987
B a l a n c e a t September 30, 2010	33,105	\$43	\$ 450,655	\$ (380,255)	\$ (292)		(200)	\$(2,741)	\$67,410
	Common Stock		Additional		Accumulated Other Comprehensive (Loss) Income		Treasury Stock		Total
	Shares	Amount	Paid-In Capital	Accumulated Deficit			Shares	Amount	
Balance at December 31, 2008	30,807	\$40	\$ 422,085	\$ (298,718)	\$ (1,297)		(200)	\$(2,741)	\$119,369

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Comprehensive loss:

Net loss	-	-	-	(29,973)	-	-	-	(29,973)
Net change in unrealized loss on marketable securities	-	-	-	-	1,001	-	-	1,001
Total comprehensive loss								(28,972)
Compensation expenses for share-based payment arrangements	-	-	10,281	-	-	-	-	10,281
Issuance of restricted stock, net of forfeitures	135	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	777	1	3,820	-	-	-	-	3,821
B a l a n c e a t								
September 30, 2009	31,719	\$41	\$ 436,186	\$ (328,691)	\$ (296)	(200)	\$(2,741)	\$104,499

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (50,925)	\$ (29,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,283	3,633
Write-off of fixed assets	-	194
Amortization of discounts, net of premiums, on marketable securities	-	883
Expenses for share-based compensation awards	7,726	10,281
Gain on sale of marketable securities	-	(237)
Changes in assets and liabilities:		
Decrease in accounts receivable	3,045	640
(Increase) decrease in other current assets	(458)	2,368
Decrease in other assets	730	-
Increase (decrease) in accounts payable and accrued expenses	812	(155)
Decrease in deferred revenue	-	(25,693)
Increase (decrease) in other liabilities	1,718	(69)
Net cash used in operating activities	(35,069)	(38,128)
Cash flows from investing activities:		
Capital expenditures	(2,127)	(836)
Sales/maturities of marketable securities	1,700	80,233
Decrease in restricted cash	-	170
Net cash (used in) provided by investing activities	(427)	79,567
Cash flows from financing activities:		
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	2,987	3,821
Net cash provided by financing activities	2,987	3,821
Net (decrease) increase in cash and cash equivalents	(32,509)	45,260
Cash and cash equivalents at beginning of period	90,903	56,186
Cash and cash equivalents at end of period	\$ 58,394	\$ 101,446

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

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PROGENICS PHARMACEUTICALS, INC.

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

1. Interim Financial Statements

Progenics Pharmaceuticals, Inc. is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward gastroenterology, oncology and infectious diseases.

Progenics commenced principal operations in 1988, became publicly traded in 1997 and throughout has been engaged primarily in research and development efforts, establishing corporate collaborations and related activities. All of our operations are conducted at our facilities in Tarrytown, New York.

Gastroenterology. Our first commercial product is RELISTOR® (methylnaltrexone bromide) subcutaneous injection, a first-in-class therapy for opioid-induced constipation approved for sale in over 50 countries worldwide, including the United States, European Union member states, Canada, Australia and Brazil. Marketing applications are pending elsewhere throughout the world.

In October 2009, we and Wyeth Pharmaceuticals terminated our 2005 RELISTOR collaboration, as a result of which we regained all worldwide rights to RELISTOR. Under our Transition Agreement, Wyeth, a Pfizer Inc. subsidiary, is now continuing to market and sell RELISTOR in the U.S. through December 31, 2010 and ex-U.S. through March 31, 2011, subject to extension and early transition options available to us. After this extended transition period, we will assume full control of and responsibility for future development and commercialization of RELISTOR.

Principal responsibility for regulatory submissions and interactions for all other formulations and presentations of RELISTOR is being transferred as part of the transition, and we have undertaken full responsibility for development of the oral formulation of the drug. We are pursuing a range of strategic options for RELISTOR, including licensing, collaboration and/or strategic alliances with world-wide or regional partners, U.S. commercialization of the currently-approved product on our own or with pharmaceutical detailing and sales organizations and/or co-promotion of the franchise with a partner using our own sales force.

Under the Transition Agreement, Wyeth is paying to us \$10.0 million in six quarterly installments through January 2011, and is continuing to pay royalties on 2010 ex-U.S. sales as provided in the 2005 collaboration agreement except to the extent certain fourth quarter financial targets are not met. No royalties are payable in respect of U.S. sales after the Transition Agreement's original U.S. Sales Period, which ended on September 30, 2010, or on any 2011 transition sales by Wyeth. Royalties or other income from RELISTOR after this transition period will be dependent on any licensing, collaboration or other arrangements we conclude with other parties, or our own commercialization efforts. Wyeth is also providing financial resources, aggregating up to approximately \$14.5 million, for development of a multi-dose pen for subcutaneous RELISTOR and required clinical studies in the pediatric setting, and is providing other assistance with respect to agreed-upon clinical, regulatory, manufacturing and supply matters. This support is ongoing and continues beyond the extended periods of Wyeth's commercialization obligations; revenue from such financial support is reported for the current period as reimbursement revenue from Wyeth under the Transition Agreement. We have agreed to purchase Wyeth's remaining inventory of subcutaneous RELISTOR at the end of the Sales Periods on agreed-upon terms and conditions. We have no further obligations to Wyeth under the 2005 collaboration agreement.

Prior to the Transition Agreement (including the 2009 period covered by this report), we received upfront, milestone and royalty payments from Wyeth, and were reimbursed for expenses we incurred in connection with the development of RELISTOR; manufacturing and commercialization expenses for RELISTOR were funded by Wyeth.

Our October 2008 out-license to Ono Pharmaceutical of the rights to subcutaneous RELISTOR in Japan is unaffected by termination of the Wyeth collaboration. Under this agreement, we received an upfront payment of \$15.0 million, and are entitled to receive potential development milestones 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.

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PROGENICS PHARMACEUTICALS, INC.

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

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. These programs are conducted through a wholly owned subsidiary, PSMA Development Company LLC. In addition to our own research and development efforts, we are pursuing strategic collaborations with biopharmaceutical companies for development of PSMA ADC.

Infectious Diseases. In the area of infectious diseases, we are developing a viral-entry inhibitor -- a humanized monoclonal antibody, PRO 140 -- for infection due to human immunodeficiency virus, the virus that causes AIDS. We are developing the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for weekly self-administration. Advancement of this program is subject to our obtaining pivotal clinical-trial funding, for which we have applied to government agencies.

Our oncology and infectious disease 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.

Funding and Financial Matters. We will require additional funding to continue our current programs to completion, which may involve collaboration agreements, licenses or sale transactions or royalty sales or financings with respect to our products and product candidates. We may also seek to raise additional capital through sales of common stock or other securities, and expect to continue funding some programs in part through government awards.

At September 30, 2010, we held \$58.4 million in cash and cash equivalents which we expect will be sufficient to fund current operations through September 30, 2011. If, however, we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend the remaining operations beyond that date.

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. Purchases may be discontinued at any time. We did not repurchase any common shares during the nine months ended September 30, 2010.

Our interim Consolidated Financial Statements included in this report have been prepared in accordance with applicable presentation requirements, and accordingly do not include all information and disclosures necessary for a presentation of our financial position, results of operations and cash flows in conformity with accounting principles generally accepted in the United States of America (“GAAP”). 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. Our interim 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, 2009. The year-end consolidated balance sheet data in these financial statements were derived from audited financial statements, but do not include all disclosures required by GAAP.

2. Revenue Recognition

We recognize revenue from all sources based on the provisions of the U.S. SEC's Staff Accounting Bulletin No. 104 and ASC 605 Revenue Recognition. There have been no material changes to our revenue recognition accounting policies as of and for the nine months ended September 30, 2010, which policies are disclosed in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009.

Under the Transition Agreement, Wyeth's license of Progenics technology is terminated except as necessary for performance of Wyeth's obligations during the transition period, and Wyeth has returned the rights to RELISTOR that we had previously granted it under the 2005 collaboration agreement. During the transition, Wyeth is obligated to pay all costs of commercialization of subcutaneous RELISTOR, including manufacturing costs, and retains all proceeds from its sale of the products, subject to royalties due to us. Decisions with respect to commercialization of the product during the transition period are to be made solely by Wyeth, which during the extended commercialization period has broader discretion to allocate resources to commercialization of RELISTOR worldwide.

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PROGENICS PHARMACEUTICALS, INC.

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

During the three and nine months ended September 30, 2010, we recognized \$55 and \$1,145, respectively, from Wyeth for expenses eligible for reimbursement under the Transition Agreement as discussed in Note 1 above.

During the three months ended September 30, 2010 and 2009, we earned royalties of \$620 and \$497, respectively, based on net sales of subcutaneous RELISTOR, and we recognized \$620 and \$509, respectively, of royalty income. During the nine months ended September 30, 2010 and 2009, we earned royalties of \$1,826 and \$1,264, respectively, based on net sales of subcutaneous RELISTOR, and we recognized \$1,826 and \$976, respectively, of royalty income. As of September 30, 2009, we had recorded a cumulative total of \$807 as deferred revenue – current. We incurred \$62 and \$49, respectively, of royalty costs and recognized \$62 and \$51, respectively, of royalty expenses during the three months ended September 30, 2010 and 2009, and we incurred \$182 and \$126, respectively, of royalty costs and recognized \$182 and \$98, respectively, of royalty expense during the nine months ended September 30, 2010 and 2009. As of September 30, 2009, we had recorded a cumulative total of \$81 of deferred royalty charges from the royalty costs incurred since we began earning royalties in the second quarter of 2008. The deferred revenue and charges at September 30, 2009 and all remaining deferred royalty revenue and charges recorded in 2009 were recognized as royalty income and expense during the fourth quarter 2009, the period in which our development obligations under the Wyeth collaboration agreement terminated.

3. 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 and nine months ended September 30, 2010 and 2009, we reported net losses and, therefore, potential common shares were not included since inclusion would have been anti-dilutive. The calculations of net loss per share, basic and diluted, are as follows:

	Net Loss (Numerator)	Weighted-Average Common Shares (Denominator)	Per Share Amount
Three months ended September 30, 2010			
Basic and diluted	\$ (17,101)	32,814	\$ (0.52)
Nine months ended September 30, 2010			
Basic and diluted	\$ (50,925)	32,444	\$ (1.57)
Three months ended September 30, 2009			
Basic and diluted	\$ (13,014)	31,428	\$ (0.41)
Nine months ended September 30, 2009			
Basic and diluted	\$ (29,973)	31,060	\$ (0.97)

For the three and nine months ended September 30, 2010 and 2009, anti-dilutive common shares excluded from diluted per share amounts consist of the following:

Three Months Ended September 30,	
2010	2009

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	Weighted- Average Number	Weighted- Average Exercise Price	Weighted- Average Number	Weighted- Average Exercise Price
Stock options	5,377	\$ 14.34	5,041	\$ 16.56
Restricted stock	11		15	
Total	5,388		5,056	

	Nine Months Ended September 30,			
	2010		2009	
	Weighted- Average Number	Weighted- Average Exercise Price	Weighted- Average Number	Weighted- Average Exercise Price
Stock options	4,949	\$ 15.52	4,624	\$ 17.85
Restricted stock	34		28	
Total	4,983		4,652	

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PROGENICS PHARMACEUTICALS, INC.

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

4. Fair Value Measurements and Marketable Securities

Our available-for-sale investment portfolio consists of marketable securities, including auction rate securities and corporate debt securities in the 2009 period covered by this report, summarized below, and are recorded at fair value in the accompanying Consolidated Balance Sheets in accordance with ASC 320 Investments – Debt and Equity Securities. The change in the fair value of these marketable securities is recorded as a component of other comprehensive loss (see Note 2. Summary of Significant Accounting Policies - Fair Value Measurements in the notes to consolidated financial statements included in our 2009 Annual Report on Form 10-K).

		September 30, 2010	December 31, 2009
Short-term			
Corporate debt securities	\$ -	\$ 1,501	
Total short-term marketable securities	-	1,501	
Long-term			
Auction rate securities	3,608	3,792	
Total long-term marketable securities	3,608	3,792	
Total marketable securities	\$ 3,608	\$ 5,293	

Available-for-sale investments measured at fair value on a recurring basis as of September 30, 2010 and December 31, 2009, are summarized by valuation hierarchy as follows:

Fair Value Measurements at September 30, 2010				
	Balance at September 30, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 50,943	\$ 50,943	\$ -	\$ -
Auction rate securities	3,608	-	-	3,608
Total	\$ 54,551	\$ 50,943	\$ -	\$ 3,608

Fair Value Measurements at December 31, 2009				
	Balance at December 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 84,169	\$ 84,169	\$ -	\$ -
Corporate debt securities	1,501	-	1,501	-
Auction rate securities	3,792	-	-	3,792
Total	\$ 89,462	\$ 84,169	\$ 1,501	\$ 3,792

At September 30, 2010, Level 3 securities, consisting of auction rate securities, were \$3.6 million and represented 6.6% of total assets measured at fair value. The fair value of these securities includes \$2.7 million of U.S. government subsidized securities collateralized by student loan obligations and \$0.9 million of investment company perpetual preferred stock. 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 reaches any scheduled maturity and is paid, or a buyer outside the auction process emerges. As of September 30, 2010, we had received all scheduled interest payments on these securities, which, in the event of auction failure, are reset according to contractual terms in the governing instruments.

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PROGENICS PHARMACEUTICALS, INC.

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

The valuation of auction rate securities held “available-for-sale” is estimated using a discounted cash flow calculation 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. As a result of re-evaluating these securities as of September 30, 2010 the temporary impairment amount decreased \$16.0 from \$308.0 at December 31, 2009, to \$292.0, which decrease is reflected as a part of other comprehensive loss. Due to the uncertainty related to the liquidity in the auction rate security market, we have classified them as long-term assets. Because we do not intend to sell these securities, and believe it is not likely that we would be required to sell these securities before recovery of principal, we do not consider these securities to be other-than-temporarily impaired at September 30, 2010 and December 31, 2009.

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 and nine months ended September 30, 2010 and 2009:

Description	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended September 30,	
	2010	2009
Balance at beginning of period	\$ 3,608	\$ 4,059
Transfers into Level 3	-	-
Total realized/unrealized gains (losses)		
Included in net loss	-	-
Included in comprehensive loss (1)	-	8
Settlements	-	(275)
Balance at end of period	\$ 3,608	\$ 3,792
(1) Total amount of unrealized gains (losses) for the period included in other comprehensive loss attributable to the change in fair market value of related assets still held at the reporting date	\$-	\$ -

Fair Value Measurements Using Significant
Unobservable Inputs
(Level 3)

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Description	For the Nine Months Ended September 30,	
	2010	2009
Balance at beginning of period	\$ 3,792	\$ 4,059
Transfers into Level 3	-	-
Total realized/unrealized gains (losses)		
Included in net loss	-	-
Included in comprehensive loss (1)	16	8
Settlements	(200)	(275)
Balance at end of period	\$ 3,608	\$ 3,792
(1) Total amount of unrealized gains (losses) for the period included in other comprehensive loss attributable to the change in fair market value of related assets still held at the reporting date	\$-	\$ -

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PROGENICS PHARMACEUTICALS, INC.

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

5. Accounts Receivable

	September 30, 2010	December 31, 2009
Research and development from collaborator	\$ 3,388	\$ 6,667
Royalties	611	589
National Institutes of Health	460	210
Other	18	56
Total	\$ 4,477	\$ 7,522

6. Accounts Payable and Accrued Expenses

	September 30, 2010	December 31, 2009
Accounts payable	\$ 192	\$ 596
Accrued consulting and clinical trial costs	3,629	2,663
Accrued payroll and related costs	1,883	1,321
Legal and professional fees	883	1,070
Other	61	186
Total	\$ 6,648	\$ 5,836

7. 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 September 30, 2010.

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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; competing products currently on the market or in development might reduce the commercial potential of our products; 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; potential product liability; intellectual property, litigation, environmental and other risks; the risk that we may not be able to enter into favorable collaboration or other relationships or that existing or future relationships may not proceed as planned; the risk that current and pending patent protection for our products may be invalid, unenforceable or challenged, or fail to provide adequate market exclusivity, or that our rights to in-licensed 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 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

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our

principal programs are directed toward gastroenterology, oncology and infectious diseases. We commenced principal operations in 1988, became publicly traded in 1997 and throughout have been engaged primarily in research and development efforts, establishing corporate collaborations and related activities.

Our sources of revenues for the three and nine months ended September 30, 2010 and 2009 have been payments under our collaboration agreements and funds from research grants from the National Institutes of Health (NIH) related to our oncology and infectious disease programs. In June 2008, we began recognizing royalty income from net sales by Wyeth of subcutaneous RELISTOR (methylnaltrexone bromide). To date, our product sales have consisted solely of limited revenues from the sale of research reagents and we expect that those sales will not significantly increase over current levels in the near future.

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A majority of our expenditures to date have been for research and development activities. Expenses for our RELISTOR research program for the three months ended September 30, 2010, increased to \$6.0 million, compared to \$1.4 million for the same period in 2009, and for the nine months ended September 30, 2010, increased to \$13.7 million, compared to \$5.7 million for the same period in 2009. Expenses for our Cancer and HIV research programs during the three months ended September 30, 2010, decreased to \$3.5 million and \$1.3 million, respectively, compared to \$4.6 million and \$2.5 million, respectively for the same period in 2009, and during the nine months ended September 30, 2010, decreased to \$11.7 million and \$4.6 million, respectively, compared to \$15.3 million and \$9.9 million, respectively, for the same period in 2009.

From January 2006 to October 2009, we recognized revenues from Wyeth (i) for reimbursement of our development expenses for RELISTOR as incurred, (ii) in respect of amortization of the \$60.0 million upfront payment we received over the period of our development obligations, and (iii) for milestones achieved during the collaboration and for royalties earned based on net sales of RELISTOR. With the reacquisition of our rights to RELISTOR in October 2009, we will be required, to the extent such tasks are not undertaken by one or more partners, to address new technological, clinical and commercial challenges, including, if we choose to sell and support or co-promote RELISTOR, hiring a sales force, developing a commercial regulatory compliance program and otherwise building a commercial infrastructure. Other than potential revenues from the RELISTOR franchise, we do not anticipate generating significant recurring revenues from royalties, product sales or otherwise in the near term.

We will require additional funding to continue our current programs to completion, which may involve collaboration agreements, licenses or sale transactions or royalty sales or financings with respect to our products and product candidates. We may also seek to raise additional capital through sales of common stock or other securities, and expect to continue funding some programs in part through government awards. Funding may not, however, be available to us on acceptable terms or at all. We continue to monitor our program expenditures, including headcount levels, in conjunction with program and program candidates that we choose or are obligated to undertake. We expect to continue to incur operating losses during the near term.

At September 30, 2010, we held \$58.4 million in cash and cash equivalents, a decrease of \$32.5 million from \$90.9 million at December 31, 2009. We expect that this amount will be sufficient to fund operations at current levels through September 30, 2011. If, however, we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend the remaining operations beyond that date.

Gastroenterology. Our first commercial product is RELISTOR, a first-in-class therapy for opioid-induced constipation approved for sale in over 50 countries worldwide, including the U.S., E.U., Canada, Australia and Brazil. Marketing applications are pending elsewhere throughout the world.

In October 2009, we and Wyeth Pharmaceuticals terminated our 2005 RELISTOR collaboration, as a result of which we regained all worldwide rights to RELISTOR. Under our Transition Agreement, Wyeth, a Pfizer Inc. subsidiary, is now continuing to market and sell RELISTOR in the U.S. through December 31, 2010 and ex-U.S. through March 31, 2011, subject to extension and early transition options available to us. After this extended transition period, we will assume full control of and responsibility for future development and commercialization of RELISTOR.

Principal responsibility for regulatory submissions and interactions for all other formulations and presentations of RELISTOR is being transferred as part of the transition, and we have undertaken full responsibility for development of the oral formulation of the drug. We are pursuing a range of strategic options for RELISTOR, including licensing, collaboration and/or strategic alliances with world-wide or regional partners, U.S. commercialization of the currently-approved product on our own or with pharmaceutical detailing and sales organizations and/or co-promotion

of the franchise with a partner using our own sales force.

Under the Transition Agreement, Wyeth is paying us \$10.0 million in six quarterly installments through January 2011, and is continuing to pay royalties on 2010 ex-U.S. sales as provided in the 2005 collaboration agreement except to the extent certain fourth quarter financial targets are not met. No royalties are payable in respect of U.S. sales after the Transition Agreement's original U.S. Sales Period, which ended on September 30, 2010, or any 2011 transition sales by Wyeth. Royalties or other income from RELISTOR after this transition period will be dependent on any licensing, collaboration or other arrangements we conclude with other parties, or our own commercialization efforts. Wyeth is also providing financial resources, aggregating up to approximately \$14.5 million, for development of a multi-dose pen for subcutaneous RELISTOR and required clinical studies in the pediatric setting, and is providing other assistance with respect to agreed-upon clinical, regulatory, manufacturing and supply matters. This support is ongoing and continues beyond the extended periods of Wyeth's commercialization obligations; revenue from such financial support is reported for the current period as reimbursement revenue from Wyeth under the Transition Agreement. We have agreed to purchase Wyeth's remaining inventory of subcutaneous RELISTOR at the end of the Sales Periods on agreed-upon terms and conditions. We have no further obligations to Wyeth under the 2005 collaboration agreement.

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Our October 2008 out-license to Ono Pharmaceutical of the rights to subcutaneous RELISTOR in Japan is unaffected by termination of the Wyeth collaboration. Ono is engaged in clinical testing in Japan of RELISTOR subcutaneous injection.

We received U.S., E.U. and Canadian approvals to market RELISTOR in pre-filled syringes, which are designed to ease preparation and administration for patients and caregivers and plan to coordinate the launch of that product with a new commercialization partner in the first half of 2011.

We are also developing subcutaneous RELISTOR for treatment of OIC outside the advanced-illness setting, in individuals with pain not related to cancer. We and Wyeth recently completed the treatment portion of a one-year, open-label safety study, results from which, together with results from a previous phase 3 efficacy trial will support planned regulatory filings in the first half of 2011 in the U.S., Europe and elsewhere for approval of RELISTOR to treat OIC in the non-cancer pain setting.

As part of our reacquisition of RELISTOR, we have taken over development responsibilities for an oral formulation of RELISTOR for the treatment of OIC in patients with non-cancer pain. In March 2010, we announced that we plan to advance oral methylnaltrexone for the treatment of OIC into late stage clinical development. In September, we announced the initiation of an international phase 3 trial of oral methylnaltrexone in non-cancer pain patients.

Our 2005 collaboration agreement with Wyeth was terminated by the October 2009 Transition Agreement, but the 2005 agreement remained in effect for the time periods prior to termination covered by this report. Prior to the Transition Agreement, we received upfront, milestone and royalty payments from Wyeth, and were reimbursed for expenses we incurred in connection with the development of RELISTOR; manufacturing and commercialization expenses for RELISTOR were funded by Wyeth. Wyeth's ex-U.S. royalty obligations continue through the end of 2010 as provided in the Transition Agreement. No royalties are payable in respect of U.S. sales after the Transition Agreement's original U.S. Sales Period, which ended on September 30, 2010, or any 2011 transition sales by Wyeth.

Under our License Agreement with Ono, in October 2008, we out-licensed rights to subcutaneous RELISTOR in Japan in return for an upfront payment of \$15.0 million and the right to receive potential development milestones 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 on terms to be negotiated separately. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in joint committees and specified technology transfer related tasks which will be at its expense, and reimbursable at the time we perform these services.

Royalty and milestone payments depend on success in development and commercialization of RELISTOR, which is dependent on many factors, such as the actions of Wyeth during the transition, Ono's efforts and those of any other business partner(s) with which we may collaborate, decisions by the FDA and other regulatory bodies, the outcome of clinical and other testing of RELISTOR, and our own efforts. Many of these matters are outside our control. In particular, we cannot guarantee that we will be able to successfully partner the RELISTOR franchise. We also cannot guarantee, in light of Wyeth's limited obligations under the Transition Agreement, its acquisition by Pfizer and its limited ongoing commercial interest in the RELISTOR franchise, that Wyeth's efforts during the transition will achieve any particular level of success in marketing and sales, regulatory approval or clinical development of subcutaneous RELISTOR.

Oncology. In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal ADC directed against 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 LLC.

Infectious Diseases and Other Research Programs. In the area of infectious diseases, we are developing a viral-entry inhibitor -- a humanized monoclonal antibody, PRO 140 -- for HIV, the virus that causes AIDS. We are developing the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for weekly self-administration. Advancement of this program is subject to our obtaining pivotal clinical-trial funding, for which we have applied to government agencies. Among our infectious disease efforts, we are evaluating second-generation hepatitis C virus entry inhibitors as possible development candidates, and we are engaged in research regarding a prophylactic vaccine against HIV infection.

We have also presented preclinical data on novel monoclonal antibodies against toxins produced by the bacterium *Clostridium difficile* (C. difficile), the leading cause of hospital-acquired diarrhea in the U.S. and a recognized growing global public health challenge. These monoclonal antibodies effectively neutralized the cell-killing activities of the toxins in vitro and significantly improved survival in a stringent animal model.

We recently presented data from preclinical studies of novel multiplex phosphoinositide 3-kinase (PI3K) inhibitors, synthetic, small-molecule compounds identified by us that, in laboratory studies, blocked both PI3K, a key regulator of one molecular signaling pathway, and MNK, an oncogenic kinase in the Ras pathway. We believe simultaneously blocking these interlinked cellular pathways may provide a strategy to combat some of the most aggressive forms of cancer.

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Our non-commercialized product candidates in oncology and infectious diseases 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 unless otherwise noted)

Our net losses were \$17,101 for the three months ended September 30, 2010, compared to \$13,014 for the same period of 2009, and \$50,925 for the nine months ended September 30, 2010, compared to \$29,973 for the same period of 2009. Revenues were \$1,967 for the three months ended September 30, 2010, compared to \$5,419 for the same period of 2009, and \$5,795 for the nine months ended September 30, 2010, compared to \$31,792 for the same period of 2009. Expenses were \$19,085 for the three months ended September 30, 2010, compared to \$18,556 for the same period of 2009, and \$56,768 for the nine months ended September 30, 2010, compared to \$63,459 for the same period of 2009. Other income totaled \$17 for the three months ended September 30, 2010, compared to \$123 for the same period of 2009, and \$48 for the nine months ended September 30, 2010, compared to \$1,694 for the same period of 2009.

Revenues:

Our sources of revenue during the three and nine months ended September 30, 2010 and 2009 included our 2005 collaboration with Wyeth (effective from January 2006 to October 2009), the Transition Agreement with Wyeth, our License Agreement with Ono, our research grants from the NIH and, to a small extent, our sale of research reagents.

Sources of Revenue	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Research and development	\$ 82	\$ 4,431	(98%)	\$ 1,175	\$ 29,206	(96%)
Royalty income	620	509	22%	1,826	976	87%
Research grants	1,234	404	205%	2,667	1,421	88%
Other revenues	31	75	(59%)	127	189	(33%)
Total	\$ 1,967	\$ 5,419	(64%)	\$ 5,795	\$ 31,792	(82%)

Research and development revenue:

Wyeth Collaboration. During the three months ended September 30, 2010 and 2009, we recognized \$55 and \$4,425, respectively, of revenue from Wyeth, consisting of (i) \$0 and \$3,240, respectively, of the \$60,000 upfront payment pursuant to the 2005 collaboration, (ii) \$0 and \$1,185, respectively, as reimbursement of expenses under the 2005 collaboration, and (iii) \$55 and \$0, respectively, as reimbursement of expenses under the 2009 Transition Agreement.

During the nine months ended September 30, 2010 and 2009, we recognized \$1,145 and \$14,153, respectively, of revenue from Wyeth, consisting of (i) \$0 and \$9,417, respectively, of the \$60,000 upfront payment pursuant to the 2005 collaboration, (ii) \$0 and \$4,736, respectively, as reimbursement of expenses under the 2005 collaboration, and (iii) \$1,145 and \$0, respectively, as reimbursement of expenses under the 2009 Transition Agreement.

From inception of the 2005 collaboration through December 31, 2009, we recognized the entire \$60,000 upfront payment, \$104,054 as reimbursement for our costs, and \$39,000 for non-refundable milestone payments. Under the

2009 Transition Agreement, Wyeth is providing financial support for certain development efforts which we will recognize as additional reimbursement revenue as we become entitled to it. Royalties or other income from RELISTOR after this transition period will be dependent on any licensing, collaboration or other arrangements we conclude with other parties, or our own commercialization efforts.

We recognized the \$60,000 upfront payment in accordance with the proportionate performance method, which is based on the percentage of actual effort performed on our development obligations relative to total effort expected for all of our performance obligations during the reporting periods under the arrangement. The Transition Agreement shortened the obligation period to October 2009.

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Ono License Agreement. In October 2008, we entered into a License Agreement with Ono and in November 2008, received an upfront payment of \$15,000. We are entitled to receive potential milestones and royalty payments. During the three and nine months ended September 30, 2009, we recognized \$0 and \$15,000 of the upfront payment as revenue, due to satisfying our performance obligations. During the three and nine months ended September 30, 2010 we recorded \$27 and \$30, respectively, and during the three and nine months ended September 30, 2009 we recorded \$6 and \$53, respectively, of reimbursement revenue for activities requested by Ono.

Royalty income. During the three months ended September 30, 2010 and 2009, we earned royalties from net sales by Wyeth of subcutaneous RELISTOR of \$620 and \$497, respectively, and recognized \$620 and \$509, respectively, of royalty income. During the nine months ended September 30, 2010 and 2009, we earned royalties from such net sales of \$1,826 and \$1,264, respectively, and recognized \$1,826 and \$976, respectively, of royalty income. As of September 30, 2009, we had recorded a cumulative total of \$807 as deferred revenue – current. This amount and all remaining deferred royalty revenue recorded in 2009, was recognized as royalty income during the fourth quarter of 2009, when the 2005 collaboration agreement terminated. Royalties from net sales by Wyeth of RELISTOR, as defined, are based on royalty rates under our 2005 collaboration, ranging up to 30% of U.S. and 25% of foreign net sales at the highest sales levels.

Global net sales of RELISTOR were \$4.1 million for the three months ended September 30, 2010, comprised of \$2.4 million of U.S. and \$1.7 million of ex-U.S. net sales. Global net sales were \$3.3 million for the three months ended September 30, 2009, with U.S. and ex-U.S. net sales constituting \$1.8 million and \$1.5 million, respectively. Global net sales of RELISTOR were \$12.2 million for the nine months ended September 30, 2010, comprised of \$7.2 million of U.S. and \$5.0 million of ex-U.S. net sales. Global net sales were \$8.4 million for the nine months ended September 30, 2009, with U.S. and ex-U.S. net sales constituting \$5.0 million and \$3.4 million, respectively.

Research grants. Revenues from research grants increased to (i) \$1,234 for the three months ended September 30, 2010 from \$404 for the three months ended September 30, 2009, and (ii) \$2,667 for the nine months ended September 30, 2010 from \$1,421 for the nine months ended September 30, 2009, in each case as a result of higher reimbursable expenses.

Other revenues, primarily from orders for research reagents, decreased to (i) \$31 for the three months ended September 30, 2010 from \$75 for the three months ended September 30, 2009, and (ii) \$127 for the nine months ended September 30, 2010 from \$189 for the nine months ended September 30, 2009.

Expenses:

Research and Development Expenses include scientific labor, clinical trial costs, supplies, product manufacturing costs, consulting, license fees, royalty payments and other operating expenses. Research and development expenses increased to \$13,139 for the three months ended September 30, 2010 from \$11,505 for the same period of 2009, and decreased to \$36,917 for the nine months ended September 30, 2010 from \$40,068 for the same period of 2009, and consisted of the following:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Salaries and benefits	\$4,354	\$5,222	(17%)	\$14,202	\$17,118	(17%)

Three Months: Salaries and benefits decreased due to a decline in average headcount to 135 from 168 for the three months ended September 30, 2010 and 2009, respectively, in the research and development, manufacturing and clinical departments.

Nine Months: Salaries and benefits decreased due to a decline in average headcount to 142 from 179 for the nine months ended September 30, 2010 and 2009, respectively, in the research and development, manufacturing and clinical departments.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Share-based compensation	\$1,436	\$1,766	(19%)	\$4,086	\$5,610	(27%)

Three Months: Share-based compensation decreased for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 due to lower stock option plan, restricted stock and employee stock purchase plan expenses.

Nine Months: Share-based compensation decreased for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 due to lower stock option plan, restricted stock and employee stock purchase plan expenses.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Clinical trial costs	\$2,108	\$452	366%	\$3,003	\$1,982	52%

Three Months: Clinical trial costs increased primarily due to higher expenses for (i) RELISTOR (\$1,654), from increased clinical trial activities, (ii) Cancer (\$152), from increased PSMA ADC activities partially offset by a decrease in PSMA VRP and (iii) Other (\$2), partially offset by a decrease in HIV (\$152), due to decreased PRO 140 clinical trial activities, all for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Clinical trial costs increased primarily due to higher expenses for (i) RELISTOR (\$1,280), from increased clinical trial activities, (ii) Cancer (\$395) and (iii) Other (\$1), partially offset by a decrease in HIV (\$655), due to decreased PRO 140 clinical trial activities, all for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Laboratory supplies	\$797	\$768	4%	\$1,764	\$2,324	(24%)

Three Months: Laboratory supplies increased due to higher expenses for RELISTOR (\$373), partially offset by decreases in (i) Cancer (\$171), due to a decrease in expenses for PSMA ADC, (ii) HIV (\$76), resulting from a decline in purchases of drug supplies and (iii) Other projects (\$97), all for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Laboratory supplies decreased due to lower expenses for (i) Cancer (\$523), due to a decrease in expenses for PSMA ADC, (ii) Other projects (\$370), and (iii) HIV (\$140), resulting from a decline in purchases of drug supplies, partially offset by an increase in RELISTOR (\$473), all for the nine months ended September 30, 2010

compared to the nine months ended September 30, 2009.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Contract manufacturing and subcontractors	\$1,419	\$1,424	0%	\$4,495	\$6,055	(26%)

Three Months: Contract manufacturing and subcontractors decreased due to lower external manufacturing related expenses for (i) Cancer (\$351), primarily from PSMA ADC and (ii) Other (\$171), partially offset by an increase in (i) HIV expenses (\$354), primarily from ProVax HIV vaccine and (ii) RELISTOR expenses (\$163), all for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Contract manufacturing and subcontractors decreased due to lower external manufacturing related expenses for (i) Cancer (\$1,220), primarily from PSMA ADC, (ii) HIV (\$583), primarily from PRO 140 partially offset by higher expenses for the ProVax HIV vaccine and (iii) Other (\$1,040), partially offset by an increase in RELISTOR expenses (\$1,283), all for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

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 Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Consultants	\$992	\$158	528%	\$1,793	\$765	134%

Three Months: Consultants expenses increased due to higher expenses for RELISTOR (\$806) and Cancer (\$37), partially offset by decreases in HIV (\$8) and Other projects (\$1), all for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Consultants expenses increased due to higher expenses for RELISTOR (\$1,161) and Cancer (\$49) partially offset by decreases in HIV (\$158) and Other projects (\$24), all for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

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 September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
License fees	\$110	\$136	(19%)	\$1,217	\$961	27%

Three Months: License fees decreased due to lower expenses for HIV (\$26) for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: License fees increased primarily due to higher expenses for HIV (\$396) and RELISTOR (\$10), partially offset by lower expenses for Cancer (\$150), all for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Royalty expense	\$62	\$51	22%	\$182	\$98	86%

Three Months: We incurred \$62 and \$49, respectively, of royalty costs and recognized \$62 and \$51, respectively, of royalty expenses during the three months ended September 30, 2010 and 2009. As of September 30, 2009, we had recorded a cumulative total of \$81 of deferred royalty charges from the royalty costs incurred since we began earning royalties in the second quarter of 2008 and all remaining deferred royalty charges were recognized as royalty expense during the fourth quarter of 2009, the period in which our development obligations relating to RELISTOR terminated.

Nine Months: We incurred \$182 and \$126, respectively, of royalty costs and recognized \$182 and \$98, respectively, of royalty expenses during the nine months ended September 30, 2010 and 2009. As of September 30, 2009, we had recorded a cumulative total of \$81 of deferred royalty charges from the royalty costs incurred since we began earning

royalties in the second quarter of 2008 and all remaining deferred royalty charges were recognized as royalty expense during the fourth quarter of 2009, the period in which our development obligations relating to RELISTOR terminated.

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	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2010	2009		2010	2009	
Other operating expenses	\$1,861	\$1,528	22%	\$6,175	\$5,155	20%

Three Months: Other operating expenses increased for the three months ended September 30, 2010 compared to the three months ended September 30, 2009, primarily due to increases in rent (\$352) and travel (\$44), partially offset by decreases in facilities (\$20), other operating expenses (\$42) and insurance (\$1).

Nine Months: Other operating expenses increased for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009, primarily due to increases in rent (\$1,193), insurance (\$6) and travel (\$2), partially offset by decreases in facilities (\$46) and other operating expenses (\$135).

General and Administrative Expenses include administrative labor, consulting and professional fees and other operating expenses. General and administrative expenses decreased to (i) \$5,414 for the three months ended September 30, 2010 from \$5,844 for the same period of 2009, and (ii) \$17,568 for the nine months ended September 30, 2010 from \$19,758 for the same period of 2009, as follows:

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2010	2009		2010	2009	
Salaries and benefits	\$1,710	\$2,031	(16%)	\$6,092	\$6,397	(5%)

Three Months: Salaries and benefits decreased for the three months ended September 30, 2010 compared to the same period in 2009, due to a decline in average headcount to 38 from 48, in the general and administrative departments as part of our efforts to reduce costs.

Nine Months: Salaries and benefits decreased for the nine months ended September 30, 2010 compared to the same period in 2009, due to a decline in average headcount to 40 from 50, in the general and administrative departments as part of our efforts to reduce costs, partially offset by lower bonus expenses in the prior year.

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2010	2009		2010	2009	
Share-based compensation	\$1,473	\$1,235	19%	\$3,640	\$4,671	(22%)

Three Months: Share-based compensation increased due to higher stock option plan expenses, partially offset by a decline in employee stock purchase plan and restricted stock expenses, for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Share-based compensation decreased due to a decline in restricted stock, stock option plan and employee stock purchase plan expenses, for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

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	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2010	2009		2010	2009	
Consulting and professional fees	\$1,252	\$1,660	(25%)	\$4,248	\$5,267	(19%)

Three Months: Consulting and professional fees decreased due to lower expenses for legal patent (\$594) and consultants (\$40), partially offset by higher legal, accounting and other professional expenses (\$226), all for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Consulting and professional fees decreased due to lower legal patent (\$712), consultants (\$255) and legal, accounting and other professional expenses (\$52), all for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2010	2009		2010	2009	
Other operating expenses	\$979	\$918	7%	\$3,588	\$3,423	5%

Three Months: Other operating expenses increased due to higher expenses for rent (\$117) and recruiting (\$26), which were partially offset by decreases in other operating expenses (\$44), investor relations (\$28) and conferences and seminars (\$10), all for the three months ended September 30, 2010 compared to the three months ended September 30, 2009.

Nine Months: Other operating expenses increased due to higher expenses for rent (\$399) and recruiting (\$34), partially offset by decreases in other operating expenses (\$171), investor relations (\$65), conferences and seminars (\$23) and travel (\$9), all for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009.

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2010	2009		2010	2009	
Depreciation and amortization	\$532	\$1,207	(56%)	\$2,283	\$3,633	(37%)

Three Months: Depreciation and amortization expense decreased to \$532 for the three months ended September 30, 2010 from \$1,207 for the three months ended September 30, 2009, primarily due to lower capital expenditures in 2009.

Nine Months: Depreciation and amortization expense decreased to \$2,283 for the nine months ended September 30, 2010 from \$3,633 for the nine months ended September 30, 2009, primarily due to lower capital expenditures in 2009.

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Other income:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Percent Change	2010	2009	Percent Change
Interest income	\$17	\$123	(86%)	\$48	\$1,457	(97%)

Three Months: Interest income decreased to \$17 for the three months ended September 30, 2010 from \$123 for the three months ended September 30, 2009. For the three months ended September 30, 2010 and 2009, investment income decreased to \$17 from \$180, respectively, due to lower interest rates for cash equivalents, lower average balance of cash equivalents and marketable securities in 2010 than in 2009. Amortization of premiums, net of discounts, was \$0 and (\$57) for the three months ended September 30, 2010 and 2009, respectively.

Nine Months: Interest income decreased to \$48 for the nine months ended September 30, 2010 from \$1,457 for the nine months ended September 30, 2009. For the nine months ended September 30, 2010 and 2009, investment income decreased to \$49 from \$2,045, respectively, due to lower interest rates for cash equivalents, lower average balance of cash equivalents and marketable securities in 2010 than in 2009. Amortization of premiums, net of discounts, was (\$1) and (\$588) for the nine months ended September 30, 2010 and 2009, respectively.

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. Other income also includes \$237 of gains from the sale of marketable securities in 2009.

Income Taxes:

For the three and nine months ended September 30, 2010 and 2009, we had losses both for book and tax purposes.

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 the 2005 Wyeth collaboration to finance our operations. We have funded our operations since inception through private placements of equity securities, public offerings of common stock, payments received under collaboration agreements, funding under government research grants and contracts, interest on investments, proceeds from the exercise of outstanding options and warrants, and the sale of our common stock under our two employee stock purchase plans (Purchase Plans).

We continue to monitor our expenditures, including headcount levels, in conjunction with program and product candidates that we choose or are obligated to undertake. We expect to continue to incur operating losses during the near term. 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 programs with current funds. Advancement of the PRO 140 program is subject to our obtaining pivotal clinical trial funding, for which we have applied to government agencies. We are also pursuing strategic collaborations with biopharmaceutical companies for PSMA ADC.

With the reacquisition of our rights to RELISTOR, we will be required, to the extent such tasks are not undertaken by one or more partners, to address new technological, clinical and commercial challenges, including, if we choose to sell

and support or co-promote RELISTOR, hiring a sales force, developing a commercial regulatory compliance program and otherwise building a commercial infrastructure. Under the Transition Agreement, we have agreed to purchase Wyeth's remaining inventory of subcutaneous RELISTOR at the end of its sales periods on agreed-upon terms and conditions. If we were to undertake development and commercialization of RELISTOR or any other product candidate on our own without a partner we would be required to establish manufacturing and marketing capabilities and fund a sales force, which we currently do not have.

At September 30, 2010, we held \$58.4 million in cash and cash equivalents, a decrease of \$32.5 million from \$90.9 million at December 31, 2009. We expect that this amount will be sufficient to fund current operations through September 30, 2011. If, however, we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend the remaining operations beyond that date. Our cash flow from operating activities was negative for the nine months ended September 30, 2010 and 2009 due primarily to the excess of expenditures on our research and development programs and general and administrative costs over cash received from collaborators and government grants to fund such programs, as described below.

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Sources of Cash

Operating Activities. Our collaboration with Wyeth provided us with a \$60.0 million upfront payment in December 2005. In addition, from January 2006 to October 2009, Wyeth reimbursed us for development expenses we incurred related to RELISTOR under the development plan agreed to between us. For the nine months ended September 30, 2009 we received \$4.7 million of such reimbursement. These reimbursements have ceased as a result of termination of the 2005 Wyeth collaboration.

Under the Transition Agreement, Wyeth is paying us \$10.0 million in six quarterly installments through January 2011, and is continuing to pay royalties on 2010 ex-U.S. sales as provided in the 2005 collaboration agreement except to the extent certain fourth quarter financial targets are not met. No royalties are payable in respect of U.S. sales after the Transition Agreement's original U.S. Sales Period, which ended on September 30, 2010, or any 2011 transition sales by Wyeth. Royalties or other income from RELISTOR after this transition period will be dependent on any licensing, collaboration or other arrangements we conclude with other parties, or our own commercialization efforts. Wyeth is also providing financial resources, aggregating up to approximately \$14.5 million, for development of a multi-dose pen for subcutaneous RELISTOR and required clinical studies in the pediatric setting, and is providing other assistance with respect to agreed-upon clinical, regulatory, manufacturing and supply matters. This support is ongoing and continues beyond the extended periods of Wyeth's commercialization obligations; revenue from such financial support is reported for the current period as reimbursement revenue from Wyeth under the Transition 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 milestones 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.

A substantial portion of our revenues to date has been derived from federal government grants. During the nine months ended September 30, 2010 and 2009, we recognized as revenue awards made to us by the NIH between 2008 and 2010, to partially fund our ProVax HIV vaccine, PRO 140, PSMA and C. difficile programs. In September 2010, we were awarded a three-year NIH grant totaling \$4.1 million in support of research and pre-clinical development of its humanized monoclonal antibodies against the disease-causing toxins produced by C. difficile. For the nine months ended September 30, 2010 and 2009, we recognized \$2.7 million and \$1.4 million, respectively, of revenue from all of our NIH grants. In October 2010, we were awarded \$730,000 as part of the U.S. Government's Qualifying Therapeutic Discovery Project, which provides grants or tax credits for 2009 and 2010 research aimed at creating new therapies, reducing long-term healthcare costs, and/or significantly advancing the goal of curing cancer within the next 30 years.

Changes in Accounts receivable and Accounts payable for the nine months ended September 30, 2010 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 redeem money market funds and use proceeds from maturities of marketable securities in order to provide funding for operations. A substantial portion of our cash and cash equivalents (\$58.4 million) are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee program. Our marketable

securities (\$3.6 million) consist of auction rate securities and are classified as available for sale. The securities include \$2.7 million of U.S. government subsidized securities collateralized by student loan obligations. These investments, while rated investment grade by the Standard & Poor's and Moody's rating agencies and predominantly having scheduled maturities greater than ten years, are heavily concentrated in the U.S. financial sector, which continues to be under stress.

Financing Activities. During the nine months ended September 30, 2010 and 2009, we received cash of \$3.0 million and \$3.8 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants, from the sale of our common stock under our Purchase Plans. 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.

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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 RELISTOR and our additional technologies, we will be required to fund our operations in the future through offerings of equity or debt securities, royalty or other financing agreements, U.S. commercialization or co-promotion with our own sales force, and/or 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.

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 in gastroenterology, oncology and infectious diseases, and are conducting several smaller research projects in those latter areas. Our total expenses for research and development from inception through September 30, 2010 have been approximately \$566.5 million. For various reasons, including the early stage of certain of our programs, the timing and results of our clinical trials, our dependence in certain instances on third parties and the uncertainty of the specific nature of RELISTOR-related future arrangements and relationships following termination of the Wyeth collaboration, many of which are outside of our control, we cannot estimate the total remaining costs to be incurred and timing to complete all our research and development programs.

For the nine months ended September 30, 2010 and 2009, research and development costs incurred by project were as follows:

	Nine Months Ended September 30,	
	2010	2009
	(in millions)	
RELISTOR	\$ 13.7	\$ 5.7
Cancer	11.7	15.3
HIV	4.6	9.9
Other	6.9	9.2
Total	\$ 36.9	\$ 40.1

Investing Activities. During the nine months ended September 30, 2010 and 2009, we spent \$2.1 million and \$0.8 million, respectively, on capital expenditures. The increase is primarily related to leasehold improvements placed in service during the second and third quarters of 2010.

Contractual Obligations

Our funding requirements for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of September 30, 2010 for future payments under these agreements:

	Total	2011	Payments due by September 30,		
			2012-2013	2014-2015	Thereafter
	(in millions)				
Operating leases	\$ 41.4	\$ 3.1	\$ 6.6	\$ 8.2	\$ 23.5
License and collaboration agreements (1)	85.2	1.5	3.3	5.0	75.4
Total	\$ 126.6	\$ 4.6	\$ 9.9	\$ 13.2	\$ 98.9

- (1) Based on assumed achievement of milestones covered under each agreement, the timing and payment of which is highly uncertain.

We periodically assess the scientific progress and merits of each of our programs to determine if continued research and development is commercially and 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, the duration and completion costs of our research and development programs are difficult to estimate and are subject to considerable variation. Our inability to complete research and development programs in a timely manner or failure to enter into collaborative agreements could significantly increase capital requirements and adversely affect our liquidity.

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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 consummation of 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.

Off-Balance Sheet Arrangements and Guarantees

We have no obligations under 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 consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009. 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.

There have been no material changes to our critical accounting policies and estimates as of and for the nine months ended September 30, 2010, which are disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2009 Annual Report on Form 10-K.

Recently Issued Accounting Standards

In April 2010, the FASB issued Accounting Standards Update ("ASU") 2010-17, which provides guidance on the criteria that should be met when determining whether the milestone method of revenue recognition is appropriate and this guidance is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We are currently evaluating the effect this ASU will have on our consolidated financial statements.

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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, auction rate securities and corporate debt securities (in the 2009 period covered by this report). Our investments totaled \$54.6 million at September 30, 2010, all of which had interest rates that were variable. As a result, we do not believe that our investments have a material exposure to interest-rate risk. Our marketable securities are classified as available-for-sale.

At September 30, 2010, we continue to hold approximately \$3.6 million (6.6% of total assets measured at fair value) of auction rate securities, in respect of which we have received all scheduled interest payments and which, in the event of auction failure, have interest rates 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 believe that 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 (i) timing of expected future successful auctions, (ii) collateralization of underlying assets of the security and (iii) credit quality of the security. As a result of re-evaluating these securities as of September 30, 2010 the temporary impairment amount decreased \$16.0 thousand from \$308.0 thousand at December 31, 2009 to \$292.0 thousand. A 100 basis point increase to our internal analysis would result in an insignificant increase in the temporary impairment of these securities as of the three months ended September 30, 2010.

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.

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, 2009 and our other public reports. In addition, the following risk factors have changed during the nine month period ended September 30, 2010:

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

We have incurred substantial annual losses since our inception. 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 continue to incur operating losses in the future, which could increase significantly if we attempt to develop and commercialize RELISTOR without adequate collaboration and/or financial arrangements and, at the same time, 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. Additional expenses we incur in future development and commercialization of RELISTOR may cause our losses to grow and to accelerate.

Both our immediate need to transition RELISTOR and our long-term strategy with respect to RELISTOR and our product candidates may require us to obtain additional financing. Our access to capital funding is uncertain.

Our cash diminishes and our losses grow as we spend on development and commercialization of RELISTOR and our product candidates. Additional expenses we incur in future development and commercialization of RELISTOR will result in accelerating diminution of our cash and growth of our losses to the extent those expenses are not funded from outside sources. By reacquiring the rights to RELISTOR from Wyeth, we have become responsible for the future development and commercialization of the currently-marketed drug after the transition and for new formulations. We do not have committed external sources of funding for these responsibilities, and are seeking additional external funding through collaborative, license or other agreements with one or more pharmaceutical companies. We have not completed these efforts and have not yet entered into a definitive relationship with any third party for them. To the extent we are not successful in these efforts, we will have to fund them from cash on hand. Royalties or other income from RELISTOR after Wyeth's efforts during this transition period end will be dependent on any licensing, collaboration or other arrangements we conclude with other parties, or our own commercialization efforts.

With regard to both RELISTOR and our other product candidates, we expect to continue to incur significant development expenditures. We expect that our cash on hand will be sufficient to fund operations at current levels through September 30, 2011. If, however, we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend the remaining operations beyond that date. We cannot predict how much additional funds we will need, the form any financing may take (such as securities issuance or royalty or other financing), or whether additional funds will be available at all, 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. Stresses in international markets are still affecting access to capital. 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 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.

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

Our stock price has a history of significant volatility. 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 financial and market conditions in the past two years 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, Ono and any other business partner(s) with which we may collaborate in the future regarding the development and commercialization of RELISTOR;
- developments in current or future relationships with other collaborative partners with respect to other products and candidates;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
- 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 ongoing operations;
- fluctuations in our operating results;
- the potential positive effect on share price of any purchases of common shares we may make in the future pursuant to the share repurchase program we announced in 2008, or downward pressure resulting from discontinuation of any such purchases; and
- general market conditions.

Competing products in development may adversely affect acceptance of our products.

We are aware of the following competition and potential competition to RELISTOR:

- An Adolor Corporation-GlaxoSmithKline plc collaboration received FDA approval in 2008 for ENTEREG® (alvimopan), an oral opioid antagonist for postoperative ileus indicated “to accelerate the time to upper and lower

gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis.” Adolor is also evaluating a phase 1 and early-stage compound for opioid-bowel dysfunction (OBD) in chronic-pain patients.

- A Sucampo Pharmaceuticals, Inc.-Takeda Pharmaceutical Company Limited collaboration markets AMITIZA® (lubiprostone) for chronic idiopathic (non-opioid related) constipation and recently completed two phase 3 pivotal clinical trials of this drug for OBD. AMITIZA is a selective chloride channel activator.
- In Europe, Mundipharma International Limited markets TARGIN® (oxycodone/naloxone), a combination of an opioid and a systemic opioid antagonist.
- Movetis NV, which has recently been acquired by Shire plc, has announced that it has started a phase 3 clinical trial in Europe with prucalopride in patients with constipation induced by opioid based pain medications.

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- A Nektar Therapeutics-AstraZeneca PLC collaboration recently announced phase 2 results of an oral peripheral mu-opioid receptor antagonist in patients with OIC, and is developing a related combination product. AstraZeneca is a leader in gastrointestinal medicine, and their collaboration may have a time-to-market advantage over us with respect to an oral therapy for OIC in chronic-pain patients.
- Alkermes, Inc. recently completed phase 1 clinical testing of an oral peripherally-restricted opioid antagonist, and has a combination product in preclinical testing.
- Theravance, Inc. is conducting phase 2 clinical testing of an oral peripheral mu-opioid antagonist.

Any of these approved products or product candidates may achieve a significant competitive advantage relative to our product. In any event, the existing or future marketing and sales capabilities of these competitors may impair our ability to compete effectively in the market.

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.

In the case of PRO 140, currently-approved drugs for the treatment of HIV infection and AIDS have shown efficacy alone and in conjunction with other agents, the latter of which we have not demonstrated for PRO 140. We are aware of two approved drugs, Trimeris' FUZEON® and Pfizer's SELZENTRY®, designed to treat HIV infection by blocking viral entry. We are also aware of various HCV drugs in pre-clinical or clinical development.

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Item 6. Exhibits

(a) Exhibits

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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SIGNATURES

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

Date: November 8, 2010

PROGENICS PHARMACEUTICALS, INC.

By: /s/ Robert A. McKinney
Robert A. McKinney, CPA
Chief Financial Officer
Senior Vice President, Finance & Operations
and Treasurer
(Duly authorized officer of the Registrant and
Principal Financial and Accounting Officer)