PROGENICS PHARMACEUTICALS INC
Form 10-Q
November 09, 2009

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

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2009
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	13-3379479
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

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

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

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

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

Large accelerated filer ¨ Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company) 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 o No x

As of November 4, 2009 there were 31,663,459 shares of common stock, par value $.0013 per share, of the registrant outstanding.

PROGENICS PHARMACEUTICALS, INC.

INDEX

INDEX

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

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

	December 31, 2008	September 30, 2009
Assets		
Current assets:		
Cash and cash equivalents	$56,186	$101,446
Marketable securities	63,127	1,518
Accounts receivable	1,337	697
Other current assets	3,531	1,163
Total current assets	124,181	104,824
Marketable securities	22,061	3,792
Fixed assets, at cost, net of accumulated depreciation and amortization	11,071	8,080
Restricted cash	520	350
Total assets	$157,833	$117,046
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$6,496	$6,341
Deferred revenue - current	31,645	5,952
Other current liabilities	57	57
Total current liabilities	38,198	12,350
Other liabilities	266	197
Total liabilities	38,464	12,547
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $.001 par value; 20,000,000 shares authorized; issued and outstanding — none		
Common stock, $.0013 par value; 40,000,000 shares authorized; issued — 30,807,387 in 2008 and 31,718,607 in 2009	40	41
Additional paid-in capital	422,085	436,186
Accumulated deficit	(298,718)	(328,691)
Accumulated other comprehensive loss	(1,297)	(296)
Treasury stock, at cost (200,000 shares in 2008 and 2009)	(2,741)	(2,741)
Total stockholders' equity	119,369	104,499
Total liabilities and stockholders' equity	$157,833	$117,046

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

INDEX

PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2008	2009	2008	2009
Revenues:				
Research and development	$16,015	$4,431	$54,896	$29,206
Royalty income	44	509	86	976
Research grants and contract	1,377	404	5,689	1,421
Other revenues	61	75	172	189
Total revenues	17,497	5,419	60,843	31,792
Expenses:				
Research and development	21,478	11,345	68,191	39,055
License fees - research and development	305	136	1,788	961
General and administrative	8,265	5,844	22,530	19,758
Royalty expense	5	51	9	98
Depreciation and amortization	1,166	1,207	3,427	3,633
Total expenses	31,219	18,583	95,945	63,505
Operating loss	(13,722)	(13,164)	(35,102)	(31,713)
Other income:				
Interest income	1,502	123	5,028	1,457
Gain on sale of marketable securities	-	-	-	237
Gain on disposal of fixed assets	-	27	-	46
Total other income	1,502	150	5,028	1,740
Net loss	$(12,220)	$(13,014)	$(30,074)	$(29,973)
Net loss per share - basic and diluted	$(0.40)	$(0.41)	$(1.00)	$(0.97)
Weighted-average shares - basic and diluted	30,323	31,428	30,048	31,060

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

INDEX

PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2009

(amounts in thousands)
(Unaudited)

	Common Stock		Additional Paid-In		Accumulated Other Comprehensive	Treasury Stock		
	Shares	Amount	Capital	Accumulated Deficit	Income	Shares	Amount	Total
Balance at December 31, 2007	29,754	$39	$ 401,500	$ (254,046)	$ 6	-	$-	$147,499
Comprehensive loss:								
Net loss	-	-	-	(30,074)	-	-	-	(30,074)
Net change in unrealized gain on marketable securities	-	-	-	-	(2,656)	-	-	(2,656)
Total comprehensive loss:								(32,730)
Compensation expenses for share-based payment arrangements	-	-	10,899	-	-	-	-	10,899
Issuance of restricted stock, net of forfeitures	164	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	638	1	5,144	-	-	-	-	5,145
Treasury shares acquired under repurchase program	-	-	-	-	-	(200)	(2,741)	(2,741)
Balance at September 30, 2008	30,556	$40	$ 417,543	$ (284,120)	$ (2,650)	(200)	$(2,741)	$128,072

	Common Stock		Additional Paid-In		Accumulated Other Comprehensive (Loss)	Treasury Stock		
	Shares	Amount	Capital	Accumulated Deficit	Income	Shares	Amount	Total

Balance at December 31, 2008	30,807	$40	$ 422,085	$ (298,718)	$ (1,297)	(200)	$(2,741)	$119,369
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
Balance at 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 condensed consolidated financial statements.

INDEX

PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2008	2009
Cash flows from operating activities:		
Net loss	$(30,074)	$(29,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,427	3,633
Write-off of fixed assets, net of gain on disposal	-	194
Amortization of discounts, net of premiums, on marketable securities	620	883
Expenses for share-based compensation awards	10,899	10,281
Gain on sale of marketable securities	-	(237)
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(4,837)	640
Decrease in other current assets	322	2,368
Increase in other assets	(6)	-
Decrease in accounts payable and accrued expenses	(3,349)	(155)
Decrease in deferred revenue	(9,849)	(25,693)
Decrease in other liabilities	(69)	(69)
Net cash used in operating activities	(32,916)	(38,128)
Cash flows from investing activities:		
Capital expenditures	(2,020)	(836)
Sales/maturities of marketable securities	96,734	80,233
Purchase of marketable securities	(54,962)	-
Decrease in restricted cash	32	170
Net cash provided by investing activities	39,784	79,567
Cash flows from financing activities:		
Purchase of treasury stock	(2,741)	-
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	5,145	3,821
Net cash provided by financing activities	2,404	3,821
Net increase in cash and cash equivalents	9,272	45,260
Cash and cash equivalents at beginning of period	10,423	56,186
Cash and cash equivalents at end of period	$19,695	$101,446

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

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

1. Interim Financial Statements

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

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

Supportive Care. Our first commercial product is RELISTOR® (methylnaltrexone bromide) subcutaneous injection, a first-in-class therapy for opioid-induced constipation approved for sale in over 30 countries worldwide, including the United States, European Union member states, Canada, Australia, and Brazil. Marketing applications are pending elsewhere throughout the world.

On October 9, 2009, we and Wyeth Pharmaceuticals terminated our 2005 RELISTOR collaboration, as a result of which we are regaining all worldwide rights to RELISTOR. Under our Transition Agreement with Wyeth, there will be a transition period during which Wyeth will continue to market and sell RELISTOR for a U.S. Sales Period ending September 30, 2010 and an ex-U.S. Sales Period ending December 31, 2010. After the transition period, we will assume full control of and responsibility for future development and commercialization of RELISTOR. On October 14, 2009, Wyeth and Pfizer Inc. completed their previously-announced merger, and Wyeth is now a wholly owned subsidiary of Pfizer.

We are pursuing a range of strategic alternatives for RELISTOR, including licensing, collaboration, strategic alliances and U.S. commercialization or co-promotion with our own sales force, as well as continuing to seek strategic collaborations and other funding support for product candidates in our pipeline.

Under the Transition Agreement, Wyeth has agreed to pay to us the sum of $10.0 million in six quarterly installments and is continuing certain ongoing development efforts for subcutaneous RELISTOR, at its expense, through September 30, 2010. Wyeth's international sales and marketing obligations during the ex-U.S. Sales Period are subject to certain extension and early transition options available to us. Wyeth will continue to pay royalties on worldwide sales as provided in the 2005 collaboration agreement except that no royalties will be payable in respect of ex-U.S. sales during (i) the fourth quarter of 2010 to the extent certain financial targets are not met or (ii) an extended ex-U.S. Sales Period in the subject country.

We regained control of the oral form of RELISTOR upon execution of the Transition Agreement, and expect to continue development as the transition progresses. Principal responsibility for regulatory submissions and interactions for all other formulations and presentations of RELISTOR will be transferred during and as part of the transition. Wyeth is also providing financial resources, aggregating up to approximately $14.5 million, and/or other assistance with respect to agreed-upon regulatory, manufacturing and supply matters. 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.

Prior to the Transition Agreement (including the periods 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 our License Agreement with Ono, we received an upfront payment of $15.0 million, and are entitled to receive potential milestones, upon achievement of development responsibilities by Ono, of up to $20.0 million, commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. Ono also has the option to acquire from us the rights to develop and commercialize in Japan other formulations of RELISTOR, including intravenous and oral forms, on terms to be negotiated separately. In June 2009, Ono began clinical testing in Japan of RELISTOR subcutaneous injection.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

Future royalty and milestone payments will depend on success in continued development and commercialization of RELISTOR. This success will in turn be dependent on many factors, such as the actions of Wyeth during the transition, Ono's efforts, decisions by the FDA and other regulatory bodies, the outcome of clinical and other testing of RELISTOR, and our own efforts, as well as those of any business partner(s) with which we may collaborate. 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.

Virology. In the area of virology, we are developing a viral-entry inhibitor -- a humanized monoclonal antibody, PRO 140 -- for human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome, or AIDS. We are developing the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for weekly self-administration. In our hepatitis C virus efforts, we are evaluating second-generation HCV-entry inhibitors as possible development candidates. We are also engaged in research regarding prophylactic vaccines against HIV infection.

Oncology. In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal antibody-drug conjugate (ADC) directed against prostate specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. We are also developing therapeutic vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are conducted through our wholly owned subsidiary, PSMA Development Company LLC.

Our virology and oncology product candidates are not as advanced in development as RELISTOR, and we do not expect any recurring revenues from sales or otherwise with respect to these product candidates in the near term. To fund these programs, we are currently in discussions with government agencies to obtain pivotal-clinical-trial funding for PRO 140, and are pursuing strategic collaborations with biopharmaceutical companies to support development of PSMA ADC.

Funding and Financial Matters. We will require additional funding to continue our current programs to completion, which may involve collaboration agreements, license 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.

Progenics has had recurring losses since inception. At September 30, 2009, we had cash, cash equivalents and marketable securities, including non-current portion, totaling $106.8 million which we expect will be sufficient to fund current operations beyond one year. During the nine months ended September 30, 2009, we had a net loss of $30.0 million and used $38.1 million of cash in operating activities. At September 30, 2009, we had an accumulated deficit of $328.7 million.

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

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, 2009.

Our interim Condensed Consolidated Financial Statements included in this report have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of our financial position, results of operations and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect (1) all adjustments, consisting primarily of normal recurring accruals, and (2) events or transactions from the balance sheet date through November 9, 2009 (issuance date), necessary for a fair statement of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. These financial statements should be read in conjunction with the financial statements and notes thereto contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Terms used but not defined herein have the meanings ascribed to them in that Annual Report. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (“GAAP”).

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

In July 2009, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 168 ("FAS 168") "The FASB Accounting Standards Codification TM and the Hierarchy of Generally Accepted Accounting Principles" which became the source of authoritative accounting principles recognized by the FASB to be applied to nongovernmental entities in the preparation of financial statements in conformity with GAAP. Rules and interpretative releases of the U.S. Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. We adopted FAS 168 on July 1, 2009 and the adoption changed the way GAAP is referenced in notes to financial statements and management's discussion and analysis of financial condition and results of operations. Starting with this Form 10-Q, GAAP references herein follow the FASB Accounting Standards Codification TM ("ASC") structure.

2. Revenue Recognition

We are recognizing revenue in connection with our collaborations under the SEC's Staff Accounting Bulletin ("SAB") No. 104 ("SAB 104") "Revenue Recognition" and apply the substantive milestone method ("Substantive Milestone Method"). In accordance with ASC 605 Revenue Recognition, all of our deliverables under the 2005 Wyeth Collaboration Agreement, consisting of granting the license for RELISTOR, transfer of supply contracts with third party manufacturers, transfer of development and manufacturing know-how, and completion of development for the subcutaneous and intravenous formulations of RELISTOR in the U.S., represented one unit of accounting, since none of those components had standalone value to Wyeth prior to regulatory approval of at least one product: that unit of accounting comprised the development phase, through regulatory approval, for the subcutaneous and intravenous formulations in the U.S.

Collaborations may contain substantive milestone payments to which we apply the Substantive Milestone Method. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (i) the milestone payment is non-refundable, (ii) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (iii) substantive effort is involved in achieving the milestone, (iv) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (v) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

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

Transition Agreement with Wyeth – October 2009

The Transition Agreement provides for the termination of the 2005 Wyeth collaboration agreement and the transition to Progenics of responsibility for the development and commercialization of RELISTOR. Under it, 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 under the 2005 collaboration

agreement.

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, during the Sales Periods. Decisions with respect to commercialization of the product during the transition period are to be made solely by Wyeth.

Wyeth Collaboration Agreement – December 2005 to October 2009

We entered into the Wyeth Collaboration Agreement in 2005 for the purpose of developing and commercializing RELISTOR. This agreement was in effect until October 2009, which includes the periods covered by this report.

The Wyeth Collaboration Agreement involved three formulations of RELISTOR: (i) a subcutaneous formulation to be used in patients with opioid-induced constipation ("OIC"), (ii) an intravenous formulation to be used in patients with post-operative ileus (“POI”) and (iii) an oral formulation to be used in patients with OIC.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

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

We assessed the nature of our involvement with the committees. Our involvement in the JSC and JDC was one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. We combined the committee obligations with the other development obligations and accounted for these obligations during the development phase as a single unit of accounting. After the period during which we have developmental responsibilities, however, we assessed that the nature of our involvement with the committees as a right, rather than an obligation. We expected at the beginning of the agreement, that the activities of the committees for that period were to be focused on Wyeth's development and commercialization obligations. Our assessment was based upon the fact that we negotiated to be on the committees as an accommodation for our granting the license for RELISTOR to Wyeth.

Under the Wyeth Collaboration Agreement, we granted to Wyeth an exclusive, worldwide license, even as to us, to develop and commercialize RELISTOR and assigned the agreements for the manufacture of RELISTOR by third parties to Wyeth. Wyeth returned the rights with respect to Japan to us in connection with its election not to develop RELISTOR there and the transaction with Ono discussed in Note 1, above. We were responsible for developing the subcutaneous and intravenous formulations in the U.S. until they receive regulatory approval, while Wyeth was responsible for these formulations outside the U.S. other than Japan. Wyeth was also responsible for the development of the oral formulation worldwide excluding Japan. We transferred to Wyeth all existing supply agreements with third parties for RELISTOR and sublicensed intellectual property rights to permit Wyeth to manufacture RELISTOR, during the development and commercialization phases of the Wyeth Collaboration Agreement, in both bulk and finished form for all products worldwide. We had no further manufacturing obligations under the 2005 Collaboration. We transferred to Wyeth all know-how, as defined, related to RELISTOR.

Upon execution of the Collaboration Agreement, Wyeth made a non-refundable, non-creditable upfront payment of $60.0 million, for which we deferred revenue at December 31, 2005. As a result of the Transition Agreement, the period of our development responsibilities under the 2005 agreement ceased in the fourth quarter of 2009. We are recognizing revenue related to the upfront license payment from the first quarter of 2006 to the fourth quarter of 2009, the period during which the performance obligations are being performed using the proportionate performance method. We are recognizing revenue using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Wyeth Collaboration Agreement and such performance obligations are provided on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Under the proportionate performance method, revenue related to the upfront license payment is recognized in any period as the percent of actual effort expended in that period relative to expected total effort, which is based upon the most current budget and development plan approved by both us and Wyeth and includes all of the performance obligations under the arrangement. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. With the termination of the Wyeth Collaboration Agreement during the fourth quarter of 2009, we will recognize all of the $5.2

million unamortized remainder, which is included in deferred revenue – current, of the upfront payment during that quarter.

The amount of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 was based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amount of revenue recognized in those periods. During the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased significantly based upon a revised development budget approved by both us and Wyeth. As a result, the period over which our obligations were to extend, and over which the upfront payment was to be amortized, was extended from the end of 2008 to the end of 2009. The Transition Agreement between Wyeth and us shortened the obligation period from the end of 2009 to October 2009.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

From January 2006 to October 2009, costs for the development of RELISTOR incurred by Wyeth or us were paid by Wyeth. Wyeth had the right once annually to engage an independent public accounting firm to audit expenses for which we had been reimbursed during the prior three years. If the accounting firm concluded that any such expenses had been understated or overstated, a reconciliation was to be made. From January 2006 to October 2009, we are recognizing as research and development revenue from collaborator, amounts received from Wyeth for reimbursement of our development expenses for RELISTOR as incurred under the development plan agreed to between us and Wyeth. In addition to the upfront payment and reimbursement of our development costs, Wyeth made milestone payments to us upon the achievement of specific milestones (development related milestones for clinical and regulatory events). Upon achievement of defined substantive development milestones by us for the subcutaneous and intravenous formulations, the milestone payments were recognized as revenue.

During the three and nine months ended September 30, 2009, we recognized $3.2 million and $9.4 million, respectively, of revenue from the $60.0 million upfront payment and $1.2 million and $4.7 million, respectively, as reimbursement for our development costs, including our labor costs. During the three and nine month periods ended September 30, 2008, we recognized $2.1 million and $8.1 million, respectively, of revenue from the $60 million upfront payment and $3.9 million and $21.8 million, respectively, as reimbursement for our development costs, including our labor costs. In April and July 2008, we earned $15.0 million and $10.0 million in milestone payments upon the FDA approval of subcutaneous RELISTOR in the U.S. and the EMEA approval of subcutaneous RELISTOR for the European Union, respectively. We considered those milestones to be substantive and recognized the payments as revenue in the periods earned.

As for royalties, during the three and nine months ended September 30, 2009, we earned $497 and $1,264, respectively, based on the net sales of subcutaneous RELISTOR, and we recognized $509 and $976, respectively, of royalty income. During the three and nine months ended September 30, 2008, we earned royalties of $117 and $438, respectively, and recognized $44 and $86, respectively, of royalty income. As of September 30, 2009, we have recorded a cumulative total of $807 as deferred revenue – current, which will be recognized as royalty income during the fourth quarter of 2009, the period in which our development obligations relating to RELISTOR terminated.

We incurred $49 and $126, respectively, of royalty costs and recognized $51 and $98, respectively, of royalty expenses during the three and nine months ended September 30, 2009. We incurred $12 and $44, respectively, of royalty costs and recognized $5 and $9, respectively, of royalty expenses during the three and nine month periods ended September 30, 2008. As of September 30, 2009, we recorded a cumulative total of $81 of deferred royalty costs from the royalty costs incurred since we began earning royalties in the second quarter of 2008. The $81 of deferred royalty costs will be recognized as royalty expense during the fourth quarter of 2009, the period in which our development obligations relating to RELISTOR terminated.

Ono Agreement – October 2008

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono will own the subcutaneous filings and approvals relating to RELISTOR in Japan. In addition to the $15.0 million upfront payment from Ono, we are entitled to receive up to an additional $20.0 million, payable upon achievement by Ono of its development milestones. Ono is also obligated to pay to us royalties and commercialization milestones on sales by Ono of subcutaneous RELISTOR in Japan. Ono has the option to acquire from us the rights to develop and commercialize in Japan other formulations of

RELISTOR, including intravenous and oral forms, on terms to be negotiated separately. 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 payable to us for the services it requests, at the time we perform services for them. Revenue earned from activities we perform for Ono is recorded in research and development revenue.

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

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

3. Share-Based Payment Arrangements

We estimate the expected term of stock options granted to employees and officers (excluding our Chief Executive Officer) and directors by using historical data for these two groups. The expected term for options granted to these two groups was 5.33 and 7.3 years, respectively, in 2008 and 5.3 and 7.3 years, respectively, in the first nine months of 2009. The expected term of stock options granted to our Chief Executive Officer, separately from stock options granted to employees and officers, was 7.5 and 7.8 years in the first nine months of 2008 and 2009, respectively. The expected term for stock options granted to non-employee consultants was ten years, equal to the contractual term of those options. In making these estimates, we calculated the expected volatility based upon the period of the respective expected terms, using a dividend rate of zero (since we have never paid and do not expect to pay dividends in the future) and a risk-free rate for periods within the expected term of the option based on the U.S. Treasury yield curve in effect at the time of grant.

The assumptions we used in the Black-Scholes option pricing model to estimate the grant date fair values of stock options granted under our stock incentive plans (the “Incentive Plans”) during the nine months ended September 30, 2008 and 2009 were as follows:

	For the Nine Months Ended September 30,	
	2008	2009
Expected volatility	66% – 91%	71% – 91%
Expected dividends	zero	zero
Expected term (years)	5.33 – 10	5.3 – 10
Weighted average expected term (years)	6.87	7.41
Risk-free rate	2.44% – 3.79%	1.78% – 3.22%

During the nine months ended September 30, 2008 and 2009, the fair value of shares purchased under the two employee stock purchase plans (the “Purchase Plans”) was estimated on the date of grant in accordance with ASC 718 Compensation – Stock Compensation via the same option valuation model used for options granted under the Incentive Plans, but with the following assumptions:

	For the Nine Months Ended September 30,	
	2008	2009
Expected volatility	83%	57% – 100%
Expected dividends	zero	zero
Expected term	6 months	6 months
Risk-free rate	1.72%	0.08% – 0.38%

The total fair value of shares under all of our share-based payment arrangements that vested during the nine months ended September 30, 2008 and 2009 was $10.9 million and $10.3 million, respectively. In such periods, $5.3 million and $5.6 million, respectively, of such value was reported as research and development expense, and $5.6 million and $4.7 million, respectively, of such value was reported as general and administrative expense.

No tax benefit was recognized related to such compensation cost during the nine months ended September 30, 2008 and 2009 because we had net losses for each of those periods and the related deferred tax assets were fully offset by a valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the nine months ended September 30, 2008 and 2009.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

In applying the treasury stock method for the calculation of diluted earnings per share ("EPS"), amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted EPS calculation unless they are anti-dilutive. We incurred net losses for the three and nine months ended September 30, 2008 and 2009 and, therefore, such amounts have not been included in the calculations for those periods since they would be anti-dilutive. As a result, basic and diluted EPS are the same for each period. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls, for purposes of diluted EPS calculation, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

4. Fair Value Measurements

Our available-for-sale investment portfolio consists of marketable securities, including corporate debt securities, securities of government-sponsored entities and auction rate securities, and is recorded at fair value in the accompanying condensed consolidated balance sheets in accordance with 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 income.

Marketable securities consisted of the following:

	December 31, 2008	September 30, 2009
Short-term		
Corporate debt securities	$ 63,127	$ 1,518
Total short-term marketable securities	63,127	1,518
Long-term		
Corporate debt securities and securities of government-sponsored entities	18,002	-
Auction rate securities	4,059	3,792
Total long-term marketable securities	22,061	3,792
Total marketable securities	$ 85,188	$ 5,310

We adopted ASC 820 Fair Value Measurements and Disclosures effective January 1, 2008 and 2009, for financial assets and financial liabilities and nonfinancial assets and nonfinancial liabilities, respectively. Fair value measurements and disclosures define fair value as the price that would be received in selling an asset or paid in transferring a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement

date, and establish a framework to make the measurement of fair value more consistent and comparable. The adoption of fair value measurements and disclosures did not have a material impact on our financial position or results of operations.

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

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

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

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

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

The following tables present our available-for-sale investments measured at fair value on a recurring basis as of December 31, 2008 and September 30, 2009, classified by valuation hierarchy (discussed above):

		Fair Value Measurements at December 31, 2008		
Investment Type	Balance at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 43,859	$ 43,859	$ -	$ -
Corporate debt securities and securities of government-sponsored entities	81,129	-	81,129	-
Auction rate securities	4,059	-	-	4,059
Total	$ 129,047	$ 43,859	$ 81,129	$ 4,059

		Fair Value Measurements at September 30, 2009		
Investment Type	Balance at September 30, 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	$ 98,156	$ 98,156	$ -	$ -
Corporate debt securities	1,518	-	1,518	-
Auction rate securities	3,792	-	-	3,792
Total	$ 103,466	$ 98,156	$ 1,518	$ 3,792

At September 30, 2009 we hold $3.8 million (3.7% of total assets measured at fair value) in auction rate securities which are classified as Level 3. The fair value of these securities includes $2.9 million of securities collateralized by student loan obligations subsidized by the U.S. government and $0.9 million of investment company perpetual preferred stock, and do not include mortgage-backed instruments. Auction rate securities are collateralized long-term instruments that were intended to provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined intervals, typically every 7 to 35 days. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders, and we were unable to dispose of those securities at auction. We will not realize cash in respect of the principal amount of these securities until a successful

auction occurs, the issuer calls or restructures the security, the security reaches any scheduled maturity and is paid (inapplicable to the perpetual preferred mentioned above) or a buyer outside the auction process emerges. As of September 30, 2009, we have received all scheduled interest payments on these securities, which, in the event of auction failure, are reset according to the contractual terms in the governing instruments.

The valuation of auction rate securities we hold is based on Level 3 unobservable inputs which consist of our internal analysis of (i) timing of expected future successful auctions, (ii) collateralization of underlying assets of the security and (iii) credit quality of the security. We re-evaluated the valuation of these securities as of September 30, 2009 and the temporary impairment amount decreased $0.008 million from $0.316 million at December 31, 2008, to $0.308 million, which is reflected as a part of other comprehensive loss on our accompanying condensed consolidated balance sheets. These securities are held “available-for-sale” and the unrealized loss is included in other comprehensive loss. Due to the uncertainty related to the liquidity in the auction rate security market and therefore when individual positions may be liquidated, we have classified these auction rate securities as long-term assets on our accompanying condensed consolidated balance sheets.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

We continue to monitor markets for our investments and consider the impact, if any, of market conditions on the fair market value of our investments. If market conditions for our investments do not recover or if we determine that it is more likely than not that we are required to sell to fund our operations before the investments recover, we may be required to record additional losses during the remainder of 2009 or in 2010. We expect to recover the amortized cost of all of our investments at maturity. Currently, we do not anticipate having to sell these securities in order to operate our business and believe that it is not more likely than not that we will be required to sell these securities prior to recovering its cost. We do not believe the carrying values of our investments are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

For those of our financial instruments with significant Level 3 inputs (all of which are auction rate securities), the following table summarizes the activities for the three and nine months ended September 30, 2008 and 2009:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
Description	For the Three Months Ended September 30, 2008	For the Three Months Ended September 30, 2009
Balance at beginning of period	$ 6,042	$ 4,059
Transfers into Level 3	-	-
Total realized/unrealized gains (losses) (1)		
Included in net loss	-	-
Included in comprehensive income (loss)	92	8
Settlements	(800)	(275)
Balance at end of period	$ 5,334	$ 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)	
Description	For the Nine Months Ended September 30, 2008	For the Nine Months Ended September 30, 2009
Balance at beginning of period	$ -	$ 4,059
Transfers into Level 3	8,150	-

Total realized/unrealized gains (losses) (1)		
Included in net loss	-	-
Included in comprehensive income (loss)	(316)	8
Settlements	(2,500)	(275)
Balance at end of period	$ 5,334	$ 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	$ (316)	$ -

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

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

ASC 820 Fair Value Measurements and Disclosures provide additional guidance on (1) estimating fair value of an asset or liability when the volume and level of market activity for the asset or liability have significantly decreased and (2) identifying transactions that are not orderly.

ASC 320 Investments – Debt and Equity Securities change the focus of the other-than-temporary model from an entity's ability and intent to hold a debt security until recovery. Under this standard, an other-than-temporary impairment occurs for debt securities if (1) an entity has the intent to sell the security, (2) it is more likely than not that it will be required to sell the security before recovery, or (3) it does not expect to recover the entire amortized cost basis of the security.

ASC 825 Financial Instruments expand the disclosure requirements for financial instruments to interim period financial statements and requires an entity to (1) disclose the methods and significant assumptions used to estimate fair value and (2) highlight any changes of the methods and significant assumptions from prior periods.

All three updates are effective for interim and annual reporting periods ending after June 15, 2009 and our adoption did not have a material effect on our financial position or results of operations.

The following table summarizes the amortized cost basis, the aggregate fair value and gross unrealized holding gains and losses at December 31, 2008 and September 30, 2009:

	Amortized Cost Basis	Fair Value	Unrealized Holding Gains	Unrealized Holding (Losses)	Net
December 31, 2008:					
Maturities less than one year:					
Corporate debt securities	$ 63,982	$ 63,127	$ 114	$ (969)	$ (855)
Maturities between one and five years:					
Corporate debt securities	17,129	16,995	71	(205)	(134)
Government-sponsored entities	999	1,007	8	-	8
Maturities greater than ten years:					
Auction rate securities	3,200	2,944	-	(256)	(256)
Investments without stated maturity dates:					
Auction rate securities	1,175	1,115	-	(60)	(60)
	$ 86,485	$ 85,188	$ 193	$ (1,490)	$ (1,297)

	Amortized Cost Basis	Fair Value	Unrealized Holding Gains	Unrealized Holding (Losses)	Net
September 30, 2009:					
Maturities less than one year:					
Corporate debt securities	$ 1,506	$ 1,518	$ 12	$ -	$ 12

Maturities greater than ten years:					
Auction rate securities	3,100	2,852	-	(248)	(248)
Investments without stated maturity dates:					
Auction rate securities	1,000	940	-	(60)	(60)
	$ 5,606	$ 5,310	$ 12	$ (308)	$ (296)

Progenics computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the securities, adjusted for the amortization of any discount or premium.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

The following table shows the gross unrealized losses and fair value of our marketable securities with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2008 and September 30, 2009.

At December 31, 2008:

	Less than 12 Months		12 Months or Greater		Total	
Description of Securities	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$57,567	$(1,174)	$-	$-	$57,567	$(1,174)
Auction rate securities	4,059	(316)	-	-	4,059	(316)
Total	$61,626	$(1,490)	$-	$-	$61,626	$(1,490)

At September 30, 2009:

	Less than 12 Months		12 Months or Greater		Total	
Description of Securities	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Auction rate securities	$-	$-	$3,792	$(308)	$3,792	$(308)
Total	$-	$-	$3,792	$(308)	$3,792	$(308)

Other-than-temporary impairment analysis on corporate debt securities. At December 31, 2008, we owned 34 securities maturing in less than one year, with a gross unrealized loss position of $969 ($46,028 of the total fair value) and there were 9 securities in the portfolio maturing between one and two years, with a gross unrealized loss position of $205 ($11,539 of the total fair value). The severity of the unrealized losses for the securities in an unrealized loss position at December 31, 2008 was between less than one percent and 17.67 percent below amortized cost, and the weighted average duration of the unrealized losses of these securities was 6.98 months.

We have evaluated our individual corporate debt securities holdings for other-than-temporary impairment and determined that the unrealized losses as of December 31, 2008 are attributable to our purchase of corporate debt securities which traded at a premium in early 2008, and have since declined in market value. Because we do not intend to sell these securities, and believe it is not more likely than not 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 December 31, 2008.

At September 30, 2009, we owned one corporate debt security which is in an unrealized gain position and, as a result of this security being in a gain position; we do not believe it is temporarily impaired.

Other-than-temporary impairment analysis on auction rate securities. The unrealized losses in our auction rate securities investments were the result of an internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. At December 31, 2008 and

September 30, 2009, there were three and two securities with a gross unrealized loss position of $316 and $308 ($4,059 and $3,792 of the total fair value), respectively.

The severity of the unrealized losses for the auction rate securities at December 31, 2008 and September 30, 2009 was between 6 percent and 8 percent below amortized cost, and the weighted average duration of the unrealized losses for these securities was 9.25 and 19 months, respectively.

We have evaluated our individual auction rate securities holdings for other-than-temporary impairment and determined that the unrealized losses as of September 30, 2009 are attributable to uncertainty in the liquidity of the auction rate security market. Because we do not intend to sell these securities, and believe it is not more likely than not 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 December 31, 2008 and September 30, 2009.

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

The following methods and assumptions were used to estimate the fair value of each class of financial instruments at December 31, 2008 and September 30, 2009, for which it is practicable to estimate that value:

Cash and cash equivalents. We consider all highly liquid investments which have maturities of three months or less, when acquired, to be cash equivalents. For those short-term instruments, the carrying value is a reasonable estimate of fair value.

Marketable securities. Our marketable securities are considered to be “available-for-sale” and include money market funds, corporate debt securities, securities of government-sponsored entities and auction rate securities. These securities are valued based on unadjusted quoted market prices in active markets for identical securities, quoted prices for similar assets at the measurement date or inputs that are unobservable and significant to the overall fair value measurement, and involve management judgment and are recorded at fair value in our financial statements, with any unrealized gains or losses reported in comprehensive income (loss), and thus the carrying value is equal to the fair value of those instruments.

Accounts receivable. Our accounts receivable represent amounts due to Progenics from research from collaborator, royalties, research grants and contract and the sales of research reagents. These amounts are considered to be short-term as they are expected to be collected within one year and we believe their carrying value approximates fair value.

Other current assets. This class of assets is comprised of financial instruments and non-financial instruments. The financial instruments primarily consist of interest and other receivables and we believe that their carrying value is a reasonable estimate of the fair value as the receivables are expected to be settled for cash within one year.

Restricted cash. The restricted cash is collateral for a letter of credit securing lease obligations. We believe that its carrying value approximates the fair value.

Accounts payable and accrued expenses. The carrying value of our accounts payable and accrued expenses approximates the fair value, as it represents amounts due to vendors and employees, which will be satisfied within one year.

The estimated fair values of our financial instruments are as follows:

Fair Value Summary Table

	December 31, 2008		September 30, 2009	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Assets:				
Cash and cash equivalents	$ 56,186	$ 56,186	$ 101,446	$ 101,446
Marketable securities	85,188	85,188	5,310	5,310
Accounts receivable	1,337	1,337	697	697
Other current assets (net of non-financial instruments)	2,036	2,036	127	127

Restricted cash	520	520	350	350
Liabilities:				
Accounts payable and accrued expenses	6,496	6,496	6,341	6,341

5. Accounts Receivable

	December 31, 2008	September 30, 2009
National Institutes of Health	$ 1,107	$ 183
Royalties	229	497
Research and development from collaborator	-	6
Other	1	11
Total	$ 1,337	$ 697

6. Accounts Payable and Accrued Expenses

	December 31, 2008	September 30, 2009
Accounts payable	$ 899	$ 371
Accrued consulting and clinical trial costs	3,556	2,735
Accrued payroll and related costs	1,093	1,801
Legal and professional fees	925	1,385
Other	23	49
Total	$ 6,496	$ 6,341

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

7. Net Loss Per Share

Our basic net loss per share amounts have been computed by dividing net loss by the weighted-average number of common shares outstanding during the period. For the three and nine months ended September 30, 2008 and 2009, we reported net losses and, therefore, potential common shares were not included since such inclusion would have been anti-dilutive.

In June 2008, the FASB updated ASC 260 Earnings Per Share by requiring entities, when calculating EPS, to allocate earnings to unvested and contingently issuable share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents when calculating EPS and also present both basic EPS and diluted EPS pursuant to the two-class method. The update to ASC 260 Earnings Per Share is effective January 1, 2009 and requires retrospective application. We adopted this update on January 1, 2009 and the adoption had no material impact on basic and diluted earnings per share for the three and nine months ended September 30, 2008 and 2009.

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

	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Three months ended September 30, 2008			
Basic and diluted	$ (12,220)	30,323	$ (0.40)
Nine months ended September 30, 2008			
Basic and diluted	$ (30,074)	30,048	$ (1.00)
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, 2008 and 2009, potential common shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive include the following:

	Three Months Ended September 30,			
	2008		2009	
	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price
Stock options	5,071	$17.87	5,041	$16.56
Restricted stock	20		15	
Total	5,091		5,056	

	Nine Months Ended September 30,			
	2008		2009	
	Weighted Average	Weighted Average	Weighted Average	Weighted Average

	Number	Exercise Price	Number	Exercise Price
Stock options	4,826	$18.03	4,624	$17.85
Restricted stock	35		28	
Total	4,861		4,652	

INDEX

PROGENICS PHARMACEUTICALS, INC.

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

8. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive loss includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. For the three and nine months ended September 30, 2008 and 2009, the components of comprehensive loss were:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2008	2009	2008	2009
Net loss	$ (12,220)	$ (13,014)	$ (30,074)	$ (29,973)
Change in net unrealized loss on marketable securities	(2,161)	7	(2,656)	1,001
Comprehensive loss	$ (14,381)	$ (13,007)	$ (32,730)	$ (28,972)

9. Commitments and Contingencies

In the ordinary course of our business, we enter into agreements with third parties, such as business partners, clinical sites and suppliers that include indemnification provisions which, in our judgment, are normal and customary for companies in our industry sector. We generally agree to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by them with respect to our products or product candidates, use of such products or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is not limited. We have not incurred material costs to defend lawsuits or settle claims related to these provisions. As a result, the estimated fair value of liabilities relating to indemnification provisions is minimal. We have no liabilities recorded for these provisions as of September 30, 2009.

10. Impact of Recently Issued Accounting Standards

In August 2009, the FASB issued Accounting Standards Update (“ASU”) 2009-05 to provide guidance on measuring the fair value of liabilities under ASC 820 Fair Value Measurements and Disclosures. This ASU clarifies the types of liabilities to be used for a Level 1 measurement and the types of valuation techniques available for a non-Level 1 measurement and is effective for the first interim or annual period beginning after August 28, 2009. We are currently evaluating the impact this ASU will have on our financial statements.

In October 2009, the FASB issued ASU 2009-13 to address the accounting for multiple-deliverable arrangements. In an arrangement with multiple deliverables, the delivered items shall be considered a separate unit of accounting if both (i) the delivered items have value to a collaborator on a stand-alone basis, in that, the collaborator could resell the delivered items on a stand-alone basis, and (ii) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item or items is considered probable and substantially in our control. This ASU will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. We are currently evaluating the impact this ASU will have on our financial statements.

INDEX

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 U.S. Securities and Exchange Commission (SEC). In particular, we cannot assure you that RELISTOR® will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, or that any of our other programs will result in a commercial product.

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

Overview

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

diseases. Our principal programs are directed toward supportive care, virology and oncology. Progenics commenced principal operations in 1988, became publicly traded in 1997 and throughout has been engaged primarily in research and development efforts, developing manufacturing capabilities, establishing corporate collaborations and raising capital.

We have only recently begun to derive revenue from a commercial product. With the reacquisition of our rights to RELISTOR, we will be required either to enter into collaboration or other arrangements with new partners or to commercialize RELISTOR on our own. In order to commercialize RELISTOR and the other principal products that we have under development, with one or more new partners or on our own, we will be required, to the extent such tasks are not undertaken by our partner(s), to continue to address technological, clinical and commercial challenges and comply with comprehensive U.S. and ex-U.S. regulatory requirements. This will be particularly the case with the oral formulation of the drug, for which we are taking over development responsibilities as part of the Wyeth collaboration termination. We expect to incur additional operating losses, resulting in a higher cash burn rate, in the future, which could increase significantly as we expand clinical trial and other product development efforts that we choose or are obligated to undertake.

INDEX

Supportive Care. Our first commercial product is RELISTOR (methylnaltrexone bromide) subcutaneous injection, a first-in-class therapy for opioid-induced constipation, approved for sale in over 30 countries worldwide, including the United States, European Union member states, Canada, Australia and Brazil. Marketing applications are pending elsewhere throughout the world.

On October 9, 2009, we and Wyeth Pharmaceuticals terminated our 2005 RELISTOR collaboration, as a result of which we are regaining all worldwide rights to RELISTOR. Under our Transition Agreement with Wyeth, there will be a transition period during which Wyeth will continue to market and sell RELISTOR for a U.S. Sales Period ending September 30, 2010 and an ex-U.S. Sales Period ending December 31, 2010. After the transition period, we will assume full control of and responsibility for future development and commercialization of RELISTOR. On October 14, 2009, Wyeth and Pfizer Inc. completed their previously announced merger, and Wyeth is now a wholly owned subsidiary of Pfizer.

We are pursuing a range of strategic alternatives for RELISTOR, including licensing, collaboration, strategic alliances and U.S. commercialization or co-promotion with our own sales force, as well as continuing to seek strategic collaborations and other funding support for product candidates in our pipeline.

Under the Transition Agreement, Wyeth has agreed to pay to us the sum of $10.0 million in six quarterly installments and is continuing certain ongoing development efforts for subcutaneous RELISTOR, at its expense, through September 30, 2010. Wyeth's international sales and marketing obligations during the ex-U.S. Sales Period are subject to certain extension and early transition options available to us. Wyeth will continue to pay royalties on worldwide sales as provided in the 2005 collaboration agreement except that no royalties will be payable in respect of ex-U.S. sales during (i) the fourth quarter of 2010 to the extent certain financial targets are not met or (ii) an extended ex-U.S. Sales Period in the subject country.

We regained control of the oral form of RELISTOR upon execution of the Transition Agreement, and expect to continue development as the transition progresses. Principal responsibility for regulatory submissions and interactions for all other formulations and presentations of RELISTOR will be transferred during and as part of the transition. Wyeth is also providing financial resources, aggregating up to approximately $14.5 million, and/or other assistance with respect to agreed-upon regulatory, manufacturing and supply matters. 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.

Our October 2008 out-license to Ono Pharmaceutical of the rights to subcutaneous RELISTOR in Japan is unaffected by termination of the Wyeth collaboration. In June 2009, Ono began clinical testing in Japan of RELISTOR subcutaneous injection.

In August 2009, we and Wyeth announced submission to U.S. and EU regulators of applications for subcutaneous RELISTOR in a new pre-filled syringe delivery system. Pre-filled syringes are designed to ease preparation and administration for patients and caregivers and, if approved, could be available to advanced-illness patients in the U.S. and Europe as early as the first half of 2010.

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

Our 2005 collaboration with Wyeth was terminated by the Transition Agreement, but the 2005 Wyeth Collaboration Agreement was in effect during the periods 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.

At inception of the Wyeth collaboration, Wyeth paid to us a $60.0 million non-refundable upfront payment. Wyeth made $39.0 million in milestone payments thereafter. Costs for the development of RELISTOR incurred by Wyeth or us starting January 1, 2006 through termination of the 2005 collaboration agreement were paid by Wyeth. We were reimbursed by Wyeth for our development costs based on the number of our full-time equivalent employees (FTEs) devoted to the development project, all subject to Wyeth's audit rights and possible reconciliation. During the applicable royalty periods, Wyeth was obligated to pay us royalties on net sales, as defined (which included specified sales deductions), of RELISTOR by Wyeth throughout the world other than Japan, where we licensed rights to subcutaneous RELISTOR to Ono.

INDEX

We recognized revenue from Wyeth for reimbursement of our development expenses for RELISTOR as incurred during each quarter under the development plan agreed to by us and Wyeth. We also recognized revenue for a portion of the $60.0 million upfront payment we received from Wyeth, based on the proportion actually performed of the expected total effort for us to complete our development obligations, as reflected in the most recent development plan and budget approved by us and Wyeth. Starting June 2008, we began recognizing royalty income based on net sales of RELISTOR by Wyeth.

Under our License Agreement with Ono, in November 2008 we received from Ono an upfront payment of $15.0 million, and are entitled to receive potential milestones, upon achievement of development responsibilities by Ono, of up to $20.0 million, commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. 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. 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 payable to us for the services it requests, at the time we perform services for them.

Future royalty and milestone payments will depend on success in continued development and commercialization of RELISTOR. This success will in turn be dependent on many factors, such as the actions of Wyeth during the transition, Ono’s efforts, decisions by the FDA and other regulatory bodies, the outcome of clinical and other testing of RELISTOR, and our own efforts, as well as those of any business partner(s) with which we may collaborate. 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.

Virology. In the area of virology, we are developing a viral-entry inhibitor -- a humanized monoclonal antibody, PRO 140 -- for human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome, or AIDS. We are developing the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for weekly self-administration. In our hepatitis C virus infection efforts, we are evaluating second-generation HCV-entry inhibitors as possible development candidates. We are also engaged in research regarding a prophylactic vaccine against HIV infection.

Oncology. In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal antibody-drug conjugate (ADC) directed against prostate specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. We are also developing therapeutic vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are conducted through our wholly owned subsidiary, PSMA Development Company LLC.

Our virology and oncology product candidates are not as advanced in development as RELISTOR, and we do not expect any recurring revenues from sales or otherwise with respect to these product candidates in the near term. To fund these programs, we are currently in discussions with government agencies to obtain pivotal-clinical-trial funding for PRO 140, and are pursuing strategic collaborations with biopharmaceutical companies to support development of PSMA ADC.

Results of Operations (dollars in thousands)

Revenues:

Our sources of revenue during the three and nine months ended September 30, 2008 and 2009 included our Collaboration with Wyeth, our License Agreement with Ono, our research grants and contract from the National Institutes of Health (NIH) and, to a small extent, our sale of research reagents. In June 2008, we began recognizing royalty income from net sales by Wyeth of subcutaneous RELISTOR.

	Three Months Ended September 30,			Nine Months Ended September 30,		
Sources of Revenue	2008	2009	Percent Change	2008	2009	Percent Change
Research and development	$ 16,015	$ 4,431	(72%)	$ 54,896	$ 29,206	(47%)
Royalty income	44	509	1057%	86	976	1035%
Research grants and contract	1,377	404	(71%)	5,689	1,421	(75%)
Other revenues	61	75	23%	172	189	10%
Total	$ 17,497	$ 5,419	(69%)	$ 60,843	$ 31,792	(48%)

INDEX

Research and development revenue:

Wyeth Collaboration. During the three months ended September 30, 2008 and 2009, we recognized $16,015 and $4,425, respectively, of revenue from Wyeth, consisting of (i) $2,092 and $3,240, respectively, from amortization of the $60,000 upfront payment we received upon entering into our Collaboration in December 2005, (ii) $3,923 and $1,185, respectively, as reimbursement for our development expenses, and (iii) $10,000 and $0, respectively, of non-refundable milestone payments.

During the nine months ended September 30, 2008 and 2009, we recognized $54,896 and $14,153, respectively, of revenue from Wyeth, consisting of (i) $8,132 and $9,417, respectively, from amortization of the $60,000 upfront payment we received upon entering into our Collaboration in December 2005, (ii) $21,764 and $4,736, respectively, as reimbursement for our development expenses, and (iii) $25,000 and $0, respectively, of non-refundable milestone payments.

From the inception of the Wyeth Collaboration through September 30, 2009, we recognized $54,855 of revenue from the $60,000 upfront payment, $104,054 as reimbursement for our development expenses, and a total of $39,000 for non-refundable milestone payments. We do not expect to receive additional reimbursement revenue due to termination of the Wyeth collaboration. Wyeth, at its expense, is continuing certain ongoing development efforts for subcutaneous RELISTOR through September 30, 2010.

We recognize a portion of the upfront payment in a reporting period in accordance with the proportionate performance method, which is based on the percentage of actual effort performed on our development obligations in that period relative to total effort expected for all of our performance obligations under the arrangement, as reflected in the most recent development plan and budget approved by Wyeth and us. During the third quarter of 2007, a revised budget was approved, which extended our performance period to the end 2009 and, thereby, decreased the amount of revenue we are recognizing through September 30, 2009. The Transition Agreement shortened the obligation period from the end of 2009 to October 2009 and we will recognize the remaining $5.2 million of unamortized upfront payment as revenue during the fourth quarter of 2009.

Ono License Agreement. In October 2008, we entered into a License Agreement with Ono and in November 2008, received an upfront payment of $15,000. 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, upon satisfaction of our performance obligations 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. We began earning royalties from net sales by Wyeth of subcutaneous RELISTOR in June 2008. During the three months ended September 30, 2008 and 2009, we earned royalties of $117 and $497, respectively, based on net sales of RELISTOR and recognized $44 and $509, respectively, of royalty income. During the nine months ended September 30, 2008 and 2009, we earned royalties of $438 and $1,264, respectively, and recognized $86 and $976, respectively, of royalty income. As of September 30, 2009, we have recorded a cumulative total of $807 as deferred revenue – current. The $807 of deferred royalty revenue will be recognized as royalty income during the fourth quarter of 2009, the period in which our development obligations under the Wyeth Collaboration Agreement terminated. Our royalties from net sales by Wyeth of RELISTOR, as defined, are based on specified royalty rates ranging up to 30% of U.S. and 25% of foreign net sales at the highest sales levels, and increase on incremental sales as net sales in a calendar year exceed specified levels.

Global net sales of RELISTOR, which began last June, were $3.3 million for the third quarter of 2009, compared to (i) $0.8 million in the third quarter of 2008, an increase of 326% and (ii) $3.2 million in the second quarter of 2009, an increase of 2%.

U.S. RELISTOR net sales totaled $1.8 million in the third quarter of 2009, compared to (i) $0.1 million in the third quarter of 2008, an increase of 1169% and (ii) $2.0 million in the second quarter of 2009, a decrease of 10%. Non-U.S. RELISTOR net sales totaled $1.5 million in the third quarter of 2009, compared to (i) $0.7 million in the third quarter of 2008, an increase of 139% and (ii) $1.2 million in the second quarter of 2009, an increase of 22%.

Research grants and contract. In 2003, we were awarded a contract by the NIH (NIH Contract) to develop a prophylactic vaccine (ProVax) designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. Funding under the NIH Contract provided for pre-clinical research, development and early clinical testing. These funds were used principally in connection with our ProVax HIV vaccine program. Through December 31, 2008, we had recognized revenue of $15,509 from this contract, including $180 for the achievement of two milestones. In June 2009, we were awarded, commencing in the second quarter, an NIH grant for a five-year period totaling up to $14.5 million to continue this work, subject to annual funding approvals and customary compliance obligations.

INDEX

Revenues from research grants and contract from the NIH decreased from $1,377 for the three months ended September 30, 2008 to $404 for the three months ended September 30, 2009; $1,009 and $404 from grants and $368 and $0 from the NIH Contract for the three months ended September 30, 2008 and 2009, respectively. The decrease in grant and contract revenue resulted from fewer active grants and reimbursable expenses in 2009 than in 2008, and the expiration of the NIH Contract in December 2008.

Revenues from research grants and contract from the NIH decreased from $5,689 for the nine months ended September 30, 2008 to $1,421 for the nine months ended September 30, 2009; $4,185 and $1,421 from grants and $1,504, and $0 from the NIH Contract for the nine months ended September 30, 2008 and 2009, respectively. The decrease in grant and contract revenue resulted from fewer active grants and reimbursable expenses in 2009 than in 2008, and the expiration of the NIH Contract in December 2008.

Other revenues, primarily from orders for research reagents, increased from $61 for the three months ended September 30, 2008 to $75 for the three months ended September 30, 2009. Other revenues, primarily from orders for research reagents, increased from $172 for the nine months ended September 30, 2008 to $189 for the nine months ended September 30, 2009.

Expenses:

Research and Development Expenses include scientific labor, supplies, facility costs, clinical trial costs, product manufacturing costs, royalty payments and license fees. Research and development expenses, including license fees and royalty expense, decreased from $21,788 for the three months ended September 30, 2008 to $11,532 for the same period of 2009, and decreased from $69,988 for the nine months ended September 30, 2008 to $40,114 for the same period of 2009, as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Salaries and benefits (cash)	$6,138	$5,222	(15%)	$19,311	$17,118	(11%)

Three Months: Salaries and benefits (cash) decreased due to a decline in average headcount from 195 to 168 for the three months ended September 30, 2008 and 2009, respectively, in the research and development, manufacturing and clinical departments as part of our efforts to manage costs.

Nine Months: Salaries and benefits (cash) decreased due to a decline in average headcount from 197 to 179 for the nine months ended September 30, 2008 and 2009, respectively, in the research and development, manufacturing and clinical departments as part of our efforts to manage costs.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Share-based compensation (non-cash)	$1,789	$1,766	(1%)	$5,246	$5,610	7%

Three Months: Share-based compensation (non-cash) decreased due to lower restricted stock compensation and employee stock purchase plan expenses partially offset by an increase in stock option plans expenses for the three months ended September 30, 2009 compared to the three months ended September 30, 2008. See Critical Accounting Policies – Share-Based Payment Arrangements.

Nine Months: Share-based compensation (non-cash) increased due to higher restricted stock compensation and stock option plans expenses partially offset by a decrease in employee stock purchase plans expenses for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008. See Critical Accounting Policies – Share-Based Payment Arrangements.

INDEX

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Clinical trial costs	$2,932	$452	(85%)	$13,834	$1,982	(86%)

Three Months: Clinical trial costs decreased primarily due to lower expenses for (i) RELISTOR ($1,424), from reduced clinical trial activities, and (ii) HIV ($1,231), due to decreased PRO 140 clinical trial activities, partially offset by an increase in expenses for Cancer ($176), all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008.

Nine Months: Clinical trial costs decreased primarily due to lower expenses for (i) RELISTOR ($9,439), from reduced clinical trial activities, and (ii) HIV ($2,469), due to decreased PRO 140 clinical trial activities, partially offset by an increase in expenses for Cancer ($57), all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Laboratory supplies	$866	$795	(8%)	$3,024	$2,370	(22%)

Three Months: Laboratory supplies decreased due to lower expenses for (i) HIV ($349), from a decline in the purchases of drug supplies, and (ii) Other projects ($21), partially offset by an increase in Cancer ($299), due to higher expenses for PSMA, all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008.

Nine Months: Laboratory supplies decreased due to lower expenses for (i) HIV ($1,358), from a decline in the purchases of drug supplies, and (ii) Other projects ($113), partially offset by an increase in Cancer ($816), due to higher expenses for PSMA, all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Contract manufacturing and subcontractors	$7,393	$1,424	(81%)	$18,547	$6,055	(67%)

Three Months: Contract manufacturing and subcontractors decreased due to lower (i) HIV expenses ($5,621), from a decline in manufacturing expenses for PRO 140, (ii) Cancer expenses ($241), due to a decline in contract manufacturing expenses for PSMA, and (iii) RELISTOR expenses ($201), partially offset by an increase in Other expenses ($94), all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008. These expenses are related to the conduct of clinical trials, including manufacture by third parties of drug materials, testing, analysis, formulation and toxicology services, and vary as the timing and level of such services are required.

Nine Months: Contract manufacturing and subcontractors decreased due to lower (i) HIV expenses ($12,084), from a decline in manufacturing expenses for PRO 140 and (ii) RELISTOR expenses ($1,457), partially offset by increases in both Cancer ($446), due to higher contract manufacturing expenses for PSMA, and Other ($603), all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008. These expenses are related to the conduct of clinical trials, including manufacture by third parties of drug materials, testing, analysis, formulation and toxicology services, and vary as the timing and level of such services are required.

INDEX

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Consultants	$529	$158	(70%)	$3,013	$765	(75%)

Three Months:Consultants expenses decreased due to lower expenses for (i) RELISTOR ($206), and (ii) HIV ($173), partially offset by an increase in Other projects ($10), all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008. These expenses are related to the monitoring of clinical trials as well as the analysis of data from completed clinical trials and vary as the timing and level of such services are required.

Nine Months:Consultants expenses decreased due to lower expenses for (i) RELISTOR ($1,469), (ii) Cancer ($274), (iii) HIV ($275) and (iv) Other projects ($230), all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008. These expenses are related to the monitoring of clinical trials as well as the analysis of data from completed clinical trials and vary as the timing and level of such services are required.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
License fees	$305	$136	(55%)	$1,788	$961	(46%)

Three Months: License fees decreased primarily due to a decline in RELISTOR expenses ($188), partially offset by an increase in HIV ($19), all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008.

Nine Months: License fees decreased primarily due to a decline in HIV expenses ($749) and RELISTOR expenses ($212), partially offset by an increase in Cancer ($134), all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Royalty expense	$5	$51	920%	$9	$98	989%

Three Months: We incurred $12 and $49, respectively, of royalty costs and recognized $5 and $51, respectively, of royalty expenses during the three months ended September 30, 2008 and 2009. As of September 30, 2009, we 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 $81 of deferred royalty charges will be 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 $44 and $126, respectively, of royalty costs and recognized $9 and $98, respectively, of royalty expenses during the nine months ended September 30, 2008 and 2009. As of September 30, 2009, we 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 $81 of deferred royalty charges will be recognized as royalty expense during the fourth quarter 2009, the period in which our development obligations relating to RELISTOR terminated.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Other operating expenses	$1,831	$1,528	(17%)	$5,216	$5,155	(1%)

Three Months: Other operating expenses decreased for the three months ended September 30, 2009 compared to the three months ended September 30, 2008, primarily due to a decrease in computer expenses ($86), facilities ($6), travel ($46) and rent ($210), partially offset by an increase in other operating expenses ($11) and insurance ($34).

Nine Months: Other operating expenses decreased for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008, primarily due to a decrease in rent ($70), travel ($90), insurance ($70), facilities ($59) and other operating expenses ($148), partially offset by an increase in computer expenses ($376).

INDEX

General and Administrative Expenses decreased from $8,265 for the three months ended September 30, 2008 to $5,844 for the same period of 2009 and decreased from $22,530 for the nine months ended September 30, 2008 to $19,758 for the same period of 2009, as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Salaries and benefits (cash)	$2,316	$2,031	(12%)	$6,892	$6,397	(7%)

Three Months: Salaries and benefits (cash) decreased due to lower bonus expenses and a decline in salaries expenses resulting from a decrease in average headcount, from 55 to 48 for the three months ended September 30, 2008 and 2009, respectively, in the general and administrative departments as part of our efforts to manage costs.

Nine Months: Salaries and benefits (cash) decreased due to lower bonus expenses for the nine months ended September 30, 2008 and 2009, respectively, in the general and administrative departments as part of our efforts to manage costs.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Share-based compensation (non-cash)	$2,324	$1,235	(47%)	$5,654	$4,671	(17%)

Three Months: Share-based compensation (non-cash) decreased due to decreases in stock option and employee stock purchase plans expenses partially offset by higher restricted stock compensation expenses for the three months ended September 30, 2009 compared to the three months ended September 30, 2008. See Critical Accounting Policies – Share-Based Payment Arrangements.

Nine Months: Share-based compensation (non-cash) decreased due to a decrease in stock option and employee stock purchase plans expenses partially offset by higher restricted stock compensation expenses for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008. See Critical Accounting Policies – Share-Based Payment Arrangements.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Consulting and professional fees	$2,242	$1,660	(26%)	$5,791	$5,267	(9%)

Three Months: Consulting and professional fees decreased due to a decrease in consultant fees ($536), audit and compliance fees ($228), legal fees ($250) and public relations ($52), which were partially offset by an increase in

patent fees ($459) and tax accounting fees ($25), all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008.

Nine Months: Consulting and professional fees decreased due to a decrease in consulting fees ($122), patent fees ($353), audit and compliance fees ($46) and public relations fees ($102), which were partially offset by an increase in legal fees ($47) and tax accounting and payroll fees ($52), all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008.

INDEX

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Other operating expenses	$1,383	$918	(34%)	$4,193	$3,423	(18%)

Three Months: Other operating expenses decreased due to lower spending on recruiting ($30), computer software ($110), travel ($30), taxes ($89), insurance ($54), rent ($67) and other operating expenses ($107), partially offset by increases in conferences and seminars ($5) and investor relations ($17), all for the three months ended September 30, 2009 compared to the three months ended September 30, 2008.

Nine Months: Other operating expenses decreased due to lower spending on recruiting ($213), conferences and seminars ($51), travel ($52), computer software ($172), taxes ($43), insurance ($10), rent ($20) and other operating expenses ($260), partially offset by an increase in investor relations ($51), all for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Depreciation and amortization	$1,166	$1,207	4%	$3,427	$3,633	6%

Three Months: Depreciation and amortization expense increased from $1,166 for the three months ended September 30, 2008 to $1,207 for the three months ended September 30, 2009, due to fixed asset purchases in 2008.

Nine Months: Depreciation and amortization expense increased from $3,427 for the nine months ended September 30, 2008 to $3,633 for the nine months ended September 30, 2009, due to fixed asset purchases in 2008.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2009	Percent Change	2008	2009	Percent Change
Other income	$1,502	$150	(90%)	$5,028	$1,740	(65%)

Three Months: Interest income decreased from $1,502 for the three months ended September 30, 2008 to $123 for the three months ended September 30, 2009. Interest income, as reported, is primarily the result of investment income from our marketable securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those marketable securities. For the three months ended September 30, 2008 and 2009, investment income decreased from $1,816 to $180, respectively, due to a decrease in interest rates and lower average balance of cash equivalents and marketable securities in 2009 than in 2008. Amortization of premiums, net of discounts, was ($314) and ($57) for the three months ended September 30, 2008 and 2009, respectively. In addition, other income for the three months ended September 30, 2009 includes $27 of gains from sale of fixed assets.

Nine Months: Interest income decreased from $5,028 for the nine months ended September 30, 2008 to $1,457 for the nine months ended September 30, 2009. Interest income, as reported, is primarily the result of investment income from our marketable securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those marketable securities. For the nine months ended September 30, 2008 and 2009, investment income decreased from $5,648 to $2,045, respectively, due to a decrease in interest rates and lower average balance of cash equivalents and marketable securities in 2009 than in 2008. Amortization of premiums, net of discounts, was ($620) and ($588) for the nine months ended September 30, 2008 and 2009, respectively. In addition, other income for the nine months ended September 30, 2009 includes $237 of gains from sale of marketable securities and $46 of gains from sale of fixed assets.

Income Taxes:

For the three and nine months ended September 30, 2008 and 2009, we had losses both for book and tax purposes.

INDEX

Net Loss:

Our net loss was $12,220 for the three months ended September 30, 2008 compared to $13,014 for the same period of 2009, and $30,074 for the nine months ended September 30, 2008 compared to $29,973 for the same period of 2009.

Liquidity and Capital Resources

We have to date generated only modest amounts of product and royalty revenue, and consequently have relied principally on external funding and our Collaboration with Wyeth, from January 2006 to October 2009, to finance our operations. We have funded our operations since inception primarily through private placements of equity securities, payments received under collaboration agreements, public offerings of common stock, funding under government research grants and contracts, interest on investments, proceeds from the exercise of outstanding options and warrants, sale of our common stock under our two employee stock purchase plans (Purchase Plans) and a license agreement. We are currently in discussions with government agencies to obtain pivotal-clinical-trial funding to support our PRO 140 compound, and are pursuing strategic collaborations with biopharmaceutical companies to support our development plan for PSMA ADC.

At September 30, 2009, we had cash, cash equivalents and marketable securities, including non-current portion, totaling $106.8 million compared with $141.4 million at December 31, 2008. We expect that our existing cash, cash equivalents and marketable securities at September 30, 2009 are sufficient to fund current operations beyond one year. Our cash flow from operating activities was negative for the nine months ended September 30, 2008 and 2009 due primarily to the excess of expenditures on our research and development programs and general and administrative costs related to those programs over cash received from collaborators and government grants and contracts to fund such programs, as described below.

Sources of Cash

Operating Activities. Our collaboration with Wyeth provided us with a $60.0 million upfront payment in December 2005. In addition, 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, 2008 and 2009, we recorded $21.8 million and $4.7 million, respectively, of such reimbursement. We will not receive additional reimbursement revenue due to the termination of the Wyeth collaboration.

Under the Transition Agreement, Wyeth has agreed to pay us $10.0 million in six quarterly installments, and its sales and marketing obligations during the transition will continue in the United States through a U.S. Sales Period and worldwide excluding Japan through the ex-U.S. Sales Period, in accordance with an agreed-upon commercialization plan. The ex-U.S. Sales Period is subject to certain extension and early transition options available to us. Wyeth will continue to pay royalties as provided in the 2005 collaboration agreement except that no royalties will be payable in respect of ex-U.S. sales during (i) the fourth quarter of 2010 to the extent certain financial targets for that quarter are not met or (ii) an extended international sale period in the subject country. Wyeth is also continuing certain ongoing development efforts for RELISTOR, at its expense, through September 30, 2010, and is providing financial resources and/or other assistance, aggregating up to approximately $14.5 million, with respect to agreed-upon regulatory, manufacturing and supply matters.

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

RELISTOR in Japan.

We are pursuing a range of strategic alternatives for RELISTOR, including licensing, collaboration, strategic alliances and U.S. commercialization or co-promotion with our own sales force, and may also enter into other collaboration agreements, license or sale transactions or royalty sales or financings with respect to other products and product candidates. We cannot forecast with any degree of certainty, however, which products or indications, if any, will be subject to future arrangements, or how they would affect our capital requirements. The consummation of other agreements would further allow us to advance other projects with current funds.

In 2003, we were awarded a contract by the NIH to develop a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. Funding under the NIH Contract provided for pre-clinical research, development and early clinical testing. These funds were used principally in connection with our ProVax HIV vaccine program. Through December 31, 2008, we had recognized revenue of $15.5 million from this contract, including $0.2 million for the achievement of two milestones. In June 2009, we were awarded, commencing in the second quarter, an NIH grant for a five-year period totaling up to $14.5 million to continue this work, subject to annual funding approvals and customary compliance obligations.

INDEX

A substantial portion of our revenues to date has been derived from federal government grants. During the nine months ended September 30, 2008 and 2009, we recognized as revenue awards made to us by the NIH between 2004 and 2009, to partially fund some of our programs. For the nine months ended September 30, 2008 and 2009, we recognized $4.2 million and $1.4 million, respectively, of revenue from all of our NIH grants.

Changes in Accounts receivable and Accounts payable for the nine months ended September 30, 2008 and 2009 resulted from the timing of receipts from the NIH and Wyeth, and payments made to trade vendors in the normal course of business.

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

Investing Activities. We purchase and sell marketable securities in order to provide funding for operations. Our marketable securities, which include corporate debt securities and auction rate securities, are classified as available-for-sale.

A substantial portion of our cash and cash equivalents ($101.5 million) are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation’s guarantee program. Our marketable securities ($5.3 million), which include corporate debt securities and auction rate securities, are classified as available for sale and include $2.9 million of securities collateralized by student loan obligations subsidized by the U.S. government. 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 extreme stress.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at September 30, 2009, we continue to hold approximately $3.8 million of auction rate securities which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. To date, we have received all scheduled interest payments on these securities. We will not realize cash in respect of the principal amount of these securities until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid, or a buyer outside the auction process emerges.

We monitor markets for our investments, but cannot guarantee that additional losses will not be required to be recorded. Valuation of securities is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk, ongoing strength and quality of market credit and liquidity and general economic and market conditions. We do not believe the carrying values of our investments are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

Our marketable securities are purchased and, in the case of auction rate securities, sold by third-party brokers in accordance with our investment policy guidelines. Our brokerage account requires that all marketable securities be held to maturity unless authorization is obtained from us to sell earlier. In fact, prior to the second quarter of 2009, we have a history of holding all marketable securities to maturity. During the second quarter of 2009, we decided to sell a portion of our marketable securities which had scheduled maturities between the fourth quarter of 2009 and the third

quarter of 2010. The proceeds from the sales were $24.8 million resulting in a gain of $0.2 million.

We expect to recover the amortized cost of all of our investments at maturity. Because we do not anticipate having to sell these securities in order to operate our business and believe it is not more likely than not that we will be required to sell these securities before recovery of principal, we do not consider these marketable securities to be other than temporarily impaired at September 30, 2009.

Financing Activities. During the nine months ended September 30, 2008 and 2009, we received cash of $5.1 million and $3.8 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants and from the sale of our common stock under our 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.

INDEX

In 2008, we obtained approvals from the FDA, as well as European Union, Canadian, Australian, Venezuelan and other regulatory authorities, for our first commercial product, RELISTOR. We continue development and clinical trials with respect to RELISTOR and our other product candidates. Under the Transition Agreement, Wyeth, at its expense, is continuing certain ongoing development efforts for subcutaneous RELISTOR through September 30, 2010, and its sales and marketing obligations during the transition will continue in the United States through a U.S. Sales Period and worldwide excluding Japan through the ex-U.S. Sales Period, in accordance with an agreed-upon commercialization plan. The ex-U.S. Sales Period is subject to certain extension and early transition options available to us. Wyeth will continue to pay royalties as provided in the 2005 collaboration agreement except that no royalties will be payable in respect of ex-U.S. sales during (i) the fourth quarter of 2010 to the extent certain financial targets for that quarter are not met or (ii) an extended international sale period in the subject country.

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 for periods in the future, by seeking additional financing through future offerings of equity or debt securities, through collaborative, license or royalty financing agreements, U.S. commercialization or co-promotion with our own sales force or funding from additional grants and government contracts. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us may seriously jeopardize the future success of our business.

Uses of Cash

Operating Activities. The majority of our cash has been used to advance our research and development programs. We currently have major research and development programs investigating supportive care, virology and oncology, and are conducting several smaller research projects in the areas of virology and oncology. Termination of our RELISTOR collaboration with Wyeth will require us either to establish one or more new collaborative or other relationships to continue developing and commercializing RELISTOR or to undertake those efforts on our own. Wyeth is continuing certain ongoing development and commercial efforts during the transition period for subcutaneous RELISTOR, and we have assumed responsibility for development of the oral form of the drug, and expect to continue development as the transition progresses.

Our total expenses for research and development from inception through September 30, 2009 have been approximately $518.6 million. For various reasons in addition to the Wyeth collaboration termination, including the early stage of certain of our programs, the timing and results of our clinical trials and our dependence in certain instances on third parties, 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, 2008 and 2009, research and development costs incurred by project were as follows:

	Nine Months Ended September 30,	
	2008	2009
	(in millions)	
RELISTOR	$ 22.6	$ 5.7
HIV	32.6	9.9
Cancer	7.5	15.3
Other programs	7.3	9.2
Total	$ 70.0	$ 40.1

We will require additional funding to continue our research and product development programs, conduct pre-clinical studies and clinical trials, fund operating expenses, pursue regulatory approvals for our product candidates, file and prosecute patent applications and enforce or defend patent claims, if any, and fund product in-licensing and any possible acquisitions.

Under our transition arrangements with Wyeth, manufacturing and commercialization expenses for subcutaneous RELISTOR are funded by Wyeth in the U.S. through September 30, 2010 and outside the U.S. other than Japan through December 31, 2010; in Japan, development, manufacturing and commercialization expenses are required to be funded by Ono. Thereafter, we will be responsible for these activities, and, have agreed to purchase Wyeth's remaining inventory of subcutaneous RELISTOR at the end of its sales periods on agreed-upon terms and conditions.

INDEX

We are pursuing a range of strategic alternatives for RELISTOR, including licensing, collaboration, strategic alliances and U.S. commercialization or co-promotion with our own sales force. If we were to undertake development and commercialization of RELISTOR or any other product candidate on our own without a partner, however, we would be required to establish manufacturing and marketing capabilities and fund a sales force, which we currently do not have.

Our 2005 purchase of rights from our methylnaltrexone licensors extinguished our cash payments that would have been due to those licensors in the future upon the achievement of certain events, including sales of RELISTOR products. We are, however, making royalty payments and are responsible for making other payments to the University of Chicago upon the occurrence of certain events.

Investing Activities. During the nine months ended September 30, 2008 and 2009, we spent $2.0 million and $0.8 million, respectively, on capital expenditures, a reduction of $1.2 million as part of our efforts to manage costs. These expenditures have been primarily related to the purchase of laboratory equipment for our research and development projects.

Contractual Obligations

Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of September 30, 2009 for future payments under these agreements:

		Payments due by September 30,			
	Total	2010	2011-2012	2013-2014	Thereafter
			(in millions)		
Operating leases	$2.0	$0.9	$0.7	$0.4	$-
License and collaboration agreements (1)	88.2	1.7	4.7	12.8	69.0
Total	$90.2	$2.6	$5.4	$13.2	$69.0

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

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 in these programs, the duration and completion costs of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete research and development projects in a timely manner or failure to enter into collaborative agreements could significantly increase capital requirements and adversely affect our liquidity.

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

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

Off-Balance Sheet Arrangements and Guarantees

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

INDEX

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America. Our significant accounting policies are disclosed in Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2008. The selection and application of these accounting principles and methods requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as certain financial statement disclosures. On an ongoing basis, we evaluate our estimates. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our evaluation form the basis for making judgments about the carrying values of assets and liabilities that are not otherwise readily apparent. While we believe that the estimates and assumptions we use in preparing the financial statements are appropriate, these estimates and assumptions are subject to a number of factors and uncertainties regarding their ultimate outcome and, therefore, actual results could differ from these estimates.

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

Revenue Recognition. We recognize revenue from all sources based on the provisions of the SEC's Staff Accounting Bulletin (SAB) No. 104 (SAB 104) and ASC 605 Revenue Recognition.

Collaborations may contain substantive milestone payments to which we apply the substantive milestone method (Substantive Milestone Method). Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (i) the milestone payment is non-refundable, (ii) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (iii) substantive effort is involved in achieving the milestone, (iv) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (v) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

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

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

Reimbursement of costs is recognized as revenue provided the provisions of ASC 605 Revenue Recognition are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying condensed consolidated balance sheets. Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term deferred revenue. The estimate of the classification of deferred revenue as short-term or long-term is based upon management's current operating budget with the collaborator for the total effort required to complete our performance obligations under the arrangement.

Royalty revenue is recognized based upon net sales of related licensed products, as reported to us by Wyeth. Royalty revenue is recognized in the period the sales occur, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement providing for the royalty. If royalties are received when we have remaining performance obligations, they would be attributed to the services being provided under the arrangement and, therefore, recognized as such obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with our policies.

During the nine months ended September 30, 2008 and 2009, we also recognized revenue from government research grants (and contract in the 2008 period), which are used to subsidize a portion of certain of our research projects (Projects), exclusively from the NIH. We also recognized revenue from the sale of research reagents during those periods.

INDEX

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

Transition Agreement with Wyeth – October 2009

The Transition Agreement provides for the termination of the 2005 Wyeth collaboration agreement and the transition to Progenics of responsibility for the development and commercialization of RELISTOR. Under it, 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 under the 2005 collaboration agreement.

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.

Wyeth Collaboration Agreement – December 2005 to October 2009

The Wyeth Collaboration Agreement was in effect until October 2009 which includes periods covered by this report.

Our license and co-development agreement with Wyeth included a non-refundable upfront license fee, reimbursement of development costs, research and development payments based upon our achievement of clinical development milestones, contingent payments based upon the achievement by Wyeth of defined events and royalties on product sales. We recognized research revenue from Wyeth from January 1, 2006 to October 2009.

Non-refundable upfront license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and steering or other committee services, can be separated in accordance with ASC 605 Revenue Recognition. We would recognize upfront license payments as revenue upon delivery of the license only if the license had standalone value and the fair value of the undelivered performance obligations, typically including research or steering or other committee services, could be determined. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value, or (ii) have standalone value but the fair value of any of the undelivered performance obligations could not be determined, the upfront license payments would be recognized as revenue over the estimated period of when our performance obligations are performed.

We must determine the period over which our performance obligations are performed and revenue related to upfront license payments are recognized. Revenue is recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents will typically be used as the measure of performance. Under the proportionate performance method, revenue related to upfront license payments is recognized in any period as the percent of actual effort expended in that period relative to total effort for all of our

performance obligations under the arrangement. We are recognizing revenue related to the upfront license payment we received from Wyeth using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Wyeth Collaboration based upon the most current budget approved by both Wyeth and us. Such performance obligations are provided by us on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget.

INDEX

During the course of a collaboration agreement, e.g., the Wyeth collaboration, that involves a development plan and budget, the amount of the upfront license payment that is recognized as revenue in any period increases or decreases as the percentage of actual effort increases or decreases, as described above. When a new budget is approved, the remaining unrecognized amount of the upfront license fee is recognized prospectively, using the methodology described above by applying the changes in the total estimated effort or period of development that is specified in the revised approved budget. The amount of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 was based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amount of revenue recognized in those periods. During the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased significantly based upon a revised development budget approved by both us and Wyeth. As a result, the period over which our obligations were to extend, and over which the upfront payment was to be amortized, was extended from the end of 2008 to the end of 2009. The Transition Agreement between Wyeth and us shortened the obligation period from the end of 2009 to October 2009. With the termination of the Wyeth Collaboration Agreement during the fourth quarter, we will recognize all of the remaining $5.2 million unamortized upfront payment during that quarter.

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

If we are involved in a steering or other committee as part of a multiple element arrangement, we assess whether our involvement constitutes a performance obligation or a right to participate. For those committees that are deemed obligations, we will evaluate our participation along with other obligations in the arrangement and will attribute revenue to our participation through the period of our committee responsibilities. In relation to the Wyeth collaboration, we assessed the nature of our involvement with the Joint Steering Committee, Joint Development Committee and Joint Commercialization Committee. Our involvement in the first two such committees was one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. We combined the committee obligations with the other development obligations and accounted for these obligations during the development phase as a single unit of accounting. After the period during which we have developmental responsibilities, however, we assessed the nature of our involvement with the committees as a right, rather than an obligation. Our assessment was based upon the fact that we negotiated to be on these committees as an accommodation for our granting of the license for RELISTOR to Wyeth. Further, Wyeth had been granted by us an exclusive worldwide license, even as to us, to develop and commercialize RELISTOR and we had assigned the agreements for the manufacture of RELISTOR by third parties to Wyeth. Following regulatory approval of the subcutaneous and intravenous formulations of RELISTOR, Wyeth was required to continue to develop the oral formulation and to commercialize all formulations as provided in the Wyeth Collaboration Agreement, for which it was capable and responsible. We expected at the beginning of the agreement, that the activities of these committees for the period were to be focused on Wyeth’s development and commercialization obligations. As discussed in Overview – Supportive Care, we and Wyeth terminated our collaboration in October 2009, as a result of which we are regaining all worldwide rights to RELISTOR and our out-license to Ono, with respect to Japan, is unaffected by the termination of the Wyeth collaboration.

During April 2008 and July 2008, we earned $15.0 million and $10.0 million, respectively, upon achievement of non-refundable milestones anticipated in the Wyeth Collaboration; the first for the FDA approval of subcutaneous RELISTOR and the second for the European approval of subcutaneous RELISTOR. We considered those milestones to be substantive based on the significant degree of risk at the inception of the collaboration related to the conduct and successful completion of clinical trials and, therefore, of not achieving the milestones; the amount of the payment received relative to the significant costs incurred since inception of the Wyeth collaboration and amount of effort expended or the risk associated with the achievement of these milestones; and the passage of 28 and 31 months,

respectively, from inception of the collaboration to the achievement of those milestones. Therefore, we recognized the milestone payments as revenue in the respective periods in which the milestones were earned.

Ono Agreement – October 2008

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono will own the subcutaneous filings and approvals relating to RELISTOR in Japan. In addition to the $15.0 million upfront payment from Ono, we are entitled to receive up to an additional $20.0 million, payable upon achievement by Ono of its development milestones. Ono is also obligated to pay to us royalties and commercialization milestones on sales by Ono of subcutaneous RELISTOR in Japan. Ono has the option to acquire from us the rights to develop and commercialize in Japan other formulations of RELISTOR, including intravenous and oral forms, on terms to be negotiated separately. 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 payable to us for the services it requests, at the time we perform services for them. Revenue earned from activities we perform for Ono is recorded in research and development revenue.

INDEX

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

Share-Based Payment Arrangements. Our share-based compensation to employees includes non-qualified stock options, restricted stock and shares issued under our Purchase Plans, which are compensatory under ASC 718 Compensation – Stock Compensation. We account for share-based compensation to non-employees, including non-qualified stock options and restricted stock, in accordance with ASC 505 Equity.

Compensation cost for all share-based awards will be recognized in our financial statements over the related requisite service periods; usually the vesting periods for awards with a service condition. Compensation cost is based on the grant-date fair value of awards that are expected to vest. As of September 30, 2009, there was $11.8 million, $5.6 million and $0.03 million of total unrecognized compensation cost related to non-vested stock options under the plans, the non-vested shares and the Purchase Plans, respectively. Those costs are expected to be recognized over weighted average periods of 2.89 years, 1.81 years and 0.04 years, respectively. We apply a forfeiture rate to the number of unvested awards in each reporting period in order to estimate the number of awards that are expected to vest. Estimated forfeiture rates are based upon historical data on vesting behavior of employees. We adjust the total amount of compensation cost recognized for each award, in the period in which each award vests, to reflect the actual forfeitures related to that award. Changes in our estimated forfeiture rate will result in changes in the rate at which compensation cost for an award is recognized over its vesting period. We have made an accounting policy decision to use the straight-line method of attribution of compensation expense, under which the grant date fair value of share-based awards will be recognized on a straight-line basis over the total requisite service period for the total award.

Under ASC 718 Compensation – Stock Compensation, the fair value of each non-qualified stock option award is estimated on the date of grant using the Black-Scholes option pricing model, which requires input assumptions of stock price on the date of grant, exercise price, volatility, expected term, dividend rate and risk-free interest rate. For this purpose:

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

- Historical volatilities are based upon daily quoted market prices of our common stock on The NASDAQ Stock Market LLC over a period equal to the expected term of the related equity instruments. We rely only on historical volatility since it provides the most reliable indication of future volatility. Future volatility is expected to be consistent with historical; historical volatility is calculated using a simple average calculation; historical data is available for the length of the option's expected term and a sufficient number of price observations are used consistently. Since our stock options are not traded on a public market, we do not use implied volatility. For the nine months ended September 30, 2008 and 2009, the volatility of our common stock has been high, 66%-91% and 71%-91%, respectively, which is common for entities in the biotechnology industry that do not have commercial products. A higher volatility input to the Black-Scholes model increases the resulting compensation expense.

- The expected term of options granted represents the period of time that options granted are expected to be outstanding. For the nine months ended September 30, 2008 and 2009, our expected term was calculated based upon historical data related to exercise and post-termination cancellation activity. Accordingly, for grants made to employees and officers (excluding our Chief Executive Officer) and directors, we are using expected terms of 5.33 and 7.3 years and 5.3 and 7.3 years, respectively. The expected term of stock options granted to our Chief Executive Officer separately from stock options granted to employees and officers, and the expected term was 7.5 years and 7.8 years in the nine months ended September 30, 2008 and 2009. Expected term for options granted to non-employee consultants was ten years, which is the contractual term of those options. For the July 1, 2008

award, the Compensation Committee of the Board of Directors modified the form of the grant used for stock incentive awards to provide for vesting of stock incentive awards granted on that date ratably over a three-year period and for acceleration of the vesting of such awards and all previously granted and outstanding awards for any employee in the event that, following a Change in Control, such employee's employment is Terminated without Cause (as such terms are defined in our 2005 Stock Incentive Plan).

- Since we have never paid dividends and do not expect to pay dividends in the future, our dividend rate is zero.

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

INDEX

A portion of the options granted to our Chief Executive Officer on July 1, 2002, 2003, 2004 and 2005, on July 3, 2006 and on July 2, 2007 cliff vests after nine years and eleven months from the respective grant date. The July 1, 2002, 2003 and 2005 awards have fully vested. Vesting of a defined portion of each award will occur earlier if a defined performance condition is achieved; more than one condition may be achieved in any period. In accordance with ASC 718 Compensation – Stock Compensation, at the end of each reporting period, we will estimate the probability of achievement of each performance condition and will use those probabilities to determine the requisite service period of each award. The requisite service period for the award is the shortest of the explicit or implied service periods. In the case of the executive's options, the explicit service period is nine years and eleven months from the respective grant dates. The implied service periods related to the performance conditions are the estimated times for each performance condition to be achieved. Thus, compensation expense will be recognized over the shortest estimated time for the achievement of performance conditions for that award (assuming that the performance conditions will be achieved before the cliff vesting occurs). On July 1, 2008 and 2009, we granted awards (consisting of options and restricted stock in 2008 and options in 2009) to our Chief Executive Officer which vest on the basis of the achievement of specified performance or market-based milestones. The options have an exercise price equal to the closing price on our common stock on the date of grant. The awards to our Chief Executive Officer are valued using a Monte Carlo simulation and the expense related to these grants will be recognized over the shortest estimated time for the achievement of the performance or market conditions. The awards will not vest unless one of the milestones is achieved or the market condition is met. Changes in the estimate of probability of achievement of any performance or market condition will be reflected in compensation expense of the period of change and future periods affected by the change.

The fair value of shares purchased under the Purchase Plans is estimated on the date of grant in accordance with ASC 718 Compensation – Stock Compensation. The same option valuation model is used for the Purchase Plans as for non-qualified stock options, except that the expected term for the Purchase Plans is six months and the historical volatility is calculated over the six month expected term.

In applying the treasury stock method for the calculation of diluted earnings per share (EPS), amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted earnings per share calculation unless they are anti-dilutive. We incurred net losses for the nine months ended September 30, 2008 and 2009, and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for those periods. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculations, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

For the nine months ended September 30, 2008 and 2009, no tax benefit was recognized related to total compensation cost for share-based payment arrangements recognized in operations because we had net losses for those periods and the related deferred tax assets were fully offset by a valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the nine months ended September 30, 2008 and 2009.

Research and Development Expenses Including Clinical Trial Expenses. Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our contracts with various clinical investigators and clinical research organizations in connection with conducting clinical trials for our product candidates. Such costs are expensed as incurred, and are based on the expected total number of patients in the trial, the rate at which the patients enter the trial and the period over which the clinical investigators and clinical research organizations are expected to provide services. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates. The Wyeth Collaboration Agreement in which Wyeth had assumed all of the financial

responsibility for further development, mitigated those costs. In addition to clinical trial expenses, we estimate the amounts of other research and development expenses, for which invoices have not been received at the end of a period, based upon communication with third parties that have provided services or goods during the period.

Fair Value Measurements. Our available-for-sale investment portfolio consists of money market funds, corporate debt securities and auction rate securities, and is recorded at fair value in the accompanying condensed consolidated balance sheets in accordance with ASC 320 Investments – Debt and Equity Securities. The change in the fair value of these investments is recorded as a component of other comprehensive loss.

We adopted ASC 820 Fair Value Measurements and Disclosures effective January 1, 2008 for financial assets and financial liabilities. Fair value measurements and disclosures defines fair value as the price that would be received in selling an asset or paid in transferring the liability (i.e., the “exit price”) in an orderly transaction between market participants at the measurement date, and establishes a framework to make the measurement of fair value more consistent and comparable. The adoption of fair value measurements and disclosures did not have a material impact on our financial position or results of operations.

INDEX

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

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

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

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

Impact of Recently Issued Accounting Standards

In August 2009, the FASB issued Accounting Standards Update ("ASU") 2009-05 to provide guidance on measuring the fair value of liabilities under ASC 820 Fair Value Measurements and Disclosures. This ASU clarifies the types of liabilities to be used for a Level 1 measurement and the types of valuation techniques available for a non-Level 1 measurement and is effective for the first interim or annual period beginning after August 28, 2009. We are currently evaluating the impact this ASU will have on our financial statements.

In October 2009, the FASB issued ASU 2009-13 to address the accounting for multiple-deliverable arrangements. In an arrangement with multiple deliverables, the delivered items shall be considered a separate unit of accounting if both (i) the delivered items have value to a collaborator on a stand-alone basis, in that, the collaborator could resell the delivered items on a stand-alone basis, and (ii) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item or items is considered probable and substantially in our control. This ASU will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. We are currently evaluating the impact this ASU will have on our financial statements.

INDEX

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary investment objective is to preserve principal while maximizing yield without significantly increasing our risk. Our investments consist of money market funds, taxable corporate debt securities and auction rate securities. Our investments totaled $103.5 million at September 30, 2009. Approximately $1.5 million of these investments had fixed interest rates, and $102.0 million had interest rates that were variable. Our marketable securities are classified as available-for-sale.

Due to the conservative nature of our short-term fixed-interest-rate investments, we do not believe that we have a material exposure to interest-rate risk. Our fixed-interest-rate long-term investments are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair values of these investments due to differences between the market interest rate and the rate at the date of purchase of the investment. A 100 basis point increase in the September 30, 2009 market interest rates would result in a decrease of approximately $0.01 million in the market values of these investments.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at September 30, 2009, we continue to hold approximately $3.8 million (3.7% of assets measured at fair value) of auction rate securities, in respect of which we have received all scheduled interest payments, which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid or a buyer outside the auction process emerges.

We continue to monitor the market for auction rate securities and consider the impact, if any, of market conditions on the fair market value of our investments. If the auction rate securities market conditions do not recover or if we determine that it is more likely than not that we are required to sell to fund our operations before the investments recover, we may be required to record additional losses during the remainder of 2009 or 2010, which may affect our financial condition, cash flows and net loss. We believe that the failed auctions experienced to date are not a result of the deterioration of the underlying credit quality of these securities, although valuation of them is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk, ongoing strength and quality of market credit and liquidity, and general economic and market conditions. We do not believe the carrying values of these auction rate securities are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

The valuation of the auction rate securities we hold is based on an internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. We re-evaluated the valuation of these securities as of September 30, 2009 and the temporary impairment amount decreased $0.008 million from $0.316 million at December 31, 2008 to $0.308 million. A 100 basis point increase to our internal analysis would result in an increase of approximately $0.041 million in the temporary impairment of these securities as of the nine months ended September 30, 2009.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the U.S. Securities Exchange Act of 1934, that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods

specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We also established a Disclosure Committee that consists of certain members of our senior management.

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

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

INDEX

PART II — OTHER INFORMATION

Item 1A. Risk Factors

Our business and operations entail a variety of serious risks and uncertainties, including those described in Item 1A of our Form 10-K for the year ended December 31, 2008 and our other public reports. In addition, the following risk factors have changed during the quarter ended September 30, 2009:

The Transition Agreement presents us with substantial new risks. For example, if we are unable to establish satisfactory relationships with one or more partners to develop and commercialize RELISTOR worldwide, we would need to make significant investment to establish a sales and marketing infrastructure and related staff, and in the meantime may be dependent on third parties for their expertise in this area.

As a result of the termination of the Wyeth collaboration, we continue to face all of the risks to which we are currently subject as well the additional risks attendant to establishing new collaborative or other relationships with one or more partners to develop and commercialize RELISTOR or, if we are unable to do so, having sole responsibility for developing and commercializing a regulated pharmaceutical product. Even with a partner, significant investment, time and managerial resources may be required to build a commercial infrastructure to co-promote, co-market or otherwise market, sell and support a pharmaceutical product. To the extent not funded from outside sources -- and in any case prior to securing any such funding -- these efforts will increase our cash requirements and result in a higher cash burn rate, which will have a material adverse effect on our financial resources and profitability.

If, after the end of Wyeth’s involvement with the product, we undertake development and commercialization of RELISTOR without one or more partners, the financial and managerial resources necessary to transition to a commercial organization would require us to divert resources from our development efforts, including those for oral RELISTOR and our product candidates, to commercial ones. Even if we establish relationships with one or more partners for these tasks, we may have to divert resources from these programs to the extent we do not fund commercial activities in full from those external sources.

Should we choose to commercialize RELISTOR directly, even in part of the world, we may not be successful in developing an effective sales, marketing and distribution infrastructure or in achieving sufficient market acceptance. Alternatively, we may also consider contracting with a third party professional pharmaceutical detailing and sales organization to perform all or certain marketing functions. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of our products, any revenues we receive will depend in substantial part or primarily on the efforts of third parties. We may not be able to control the amount and timing of marketing resources these third parties devote to our products.

We are and will be dependent on Wyeth, Ono and other business partners to develop and commercialize RELISTOR in their respective areas, exposing us to significant risks. In particular, Wyeth has limited incentive to maximize the value of RELISTOR during the transition.

We are and will be dependent upon Wyeth (during the transition of its responsibilities to us pursuant to the Transition Agreement), Ono and any other business partner(s) with which we may collaborate in the future, in their respective territories, to perform and fund development, including clinical testing of RELISTOR, make related regulatory filings and manufacture and market products. Revenues from the sale of RELISTOR currently depend almost entirely upon the efforts of Wyeth and, in Japan, Ono. Wyeth, during the transition, and Ono have significant discretion in determining the efforts and resources they apply to sales of RELISTOR products in their territories and may not be effective in marketing such products. These considerations may apply to other business partners. Our business relationships with Wyeth, Ono and other partners may not be scientifically, clinically or commercially successful.

As a result of termination of our relationship with Wyeth, we intend to seek alternative arrangements with one or more other parties to develop and commercialize RELISTOR. We might also seek such alternative arrangements if our relationship with Ono were to terminate. We may not be able to enter into such an agreement with other suitable companies on acceptable terms or at all, in which event, in order to continue to develop and commercialize RELISTOR on our own, we would have to develop a sales and marketing organization and a distribution infrastructure, neither of which we currently have. Developing these resources would be an expensive and lengthy process and will have a material adverse effect on our financial resources and profitability. Termination of our relationship with Wyeth may also seriously compromise the development program for RELISTOR and possibly our other product candidates, as we may experience significant delays and may have to assume full funding and other responsibility for development and commercialization. Any of these outcomes would result in delays in our ability to distribute RELISTOR and would increase our expenses.

INDEX

Our relationship with Wyeth has been, and during the transition continues to be, multi-faceted and involves complex sharing of control over decisions, responsibilities, costs and benefits. Wyeth's development and commercialization obligations during the transition period are limited by the Transition Agreement and are less extensive than its obligations under the 2005 collaboration. In addition, the recently completed acquisition of Wyeth by Pfizer, which has resulted in management and personnel changes, together with the fact that by returning our RELISTOR rights, Wyeth has a limited ongoing commercial interest in the RELISTOR franchise, may affect Wyeth's performance of its obligations during the transition. We cannot guarantee that Wyeth's efforts during the transition will achieve any particular level of success in marketing and sale, regulatory approval or clinical development of RELISTOR.

Our relationship with Ono is also multi-faceted and involves complex sharing of control over decisions, responsibilities, costs and benefits.

We have had and may have future disagreements with Wyeth and Ono concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property. Both of them have significantly greater financial and managerial resources than we do, which either could draw upon in the event of a dispute. Disagreements between either of them and us could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as to extensive financial and operational consequences to us, and have a material adverse effect on our business, results of operations and financial condition. These considerations may apply to other business partners with which we may collaborate in the future.

A setback in clinical development programs could adversely affect us.

We and Wyeth continue to conduct clinical trials of RELISTOR. If the results of these or future trials are not satisfactory, we encounter problems enrolling subjects, clinical trial supply issues or other difficulties arise, or we experience setbacks in developing drug formulations, including raw material-supply, manufacturing or stability difficulties, our entire RELISTOR development program could be adversely affected, resulting in delays in trials or regulatory filings for further marketing approval. Conducting additional clinical trials or making significant revisions to our clinical development plan would lead to delays in regulatory filings. If clinical trials indicate a serious problem with the safety or efficacy of a RELISTOR product, we, Wyeth, Ono or another partner may stop development or commercialization of affected products. Since RELISTOR is our only approved product, any setback of these types could have a material adverse effect on our business, results of operations and financial condition.

Ono must conduct clinical trials with Japanese patients to obtain regulatory approval in Japan. We have not tested RELISTOR in Japanese patients, and there can be no assurance that clinical trials of RELISTOR in Japanese patients will yield results adequate for regulatory approval in Japan.

We are conducting or planning clinical trials of PRO 140, PSMA ADC and prostate cancer vaccine candidates. If the results of our future clinical studies of PRO 140 or PSMA ADC or the pre-clinical and clinical studies involving the PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved. Because our vaccine product candidates may be deemed to involve gene therapy, a relatively new technology that has not been extensively tested in humans, regulatory requirements applicable to them may be unclear, or subject to substantial regulatory review that delays the development and approval process generally.

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

We have incurred substantial losses since our inception. As of September 30, 2009, we had an accumulated deficit of $328.7 million. We have derived no significant revenues from product sales or royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur additional operating

losses in the future, which could increase significantly 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.

INDEX

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

As of September 30, 2009, we had cash, cash equivalents and marketable securities, including non-current portion, totaling $106.8 million. During the nine months ended September 30, 2009, we had a net loss of $30.0 million and cash used in operating activities was $38.1 million. 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.

Although our spending on RELISTOR has been significant during 2007, 2008 and through the third quarter of 2009, our expenses for RELISTOR have been reimbursed by Wyeth under the Wyeth Collaboration Agreement. As a result of termination of our collaboration with Wyeth, we will no longer receive such reimbursement.

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

Our access to capital funding is always uncertain. Turmoil in international markets is still affecting access to capital, exacerbating this uncertainty. Despite previous experience, we may not be able at the necessary time to obtain additional funding on acceptable terms, or at all. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize the future success of our business.

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

A substantial portion of our cash and cash equivalents are invested in U.S. Treasury money market securities. Our marketable securities, which predominantly include auction rate securities, are classified as available for sale. At September 30, 2009, we continue to hold approximately $3.8 million of auction rate securities which, in the event of auction failure, have been reset according to the contractual terms in the governing instruments. To date, we have received all scheduled interest payments on these securities. We will not realize cash in respect of the principal amount of these securities until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid, or a buyer outside the auction process emerges.

We monitor markets for our investments, but cannot guarantee that additional losses will not be required to be recorded. Valuation of securities is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk, ongoing strength and quality of market credit and liquidity and general economic and market conditions.

Our clinical trials could take longer than we expect.

Projections that we publicly announce of commencement and duration of clinical trials may not be certain. For example, we have experienced clinical trial delays in the past as a result of slower than anticipated enrollment. These delays may recur. Delays can be caused by, among other things:

- deaths or other adverse medical events involving subjects in our clinical trials;
- regulatory or patent issues;
- interim or final results of ongoing clinical trials;
- failure to enroll clinical sites as expected;

INDEX

- competition for enrollment from clinical trials conducted by others in similar indications;
- scheduling conflicts with participating clinicians and clinical institutions;
- disagreements, disputes or other matters arising from collaborations;
- our inability to obtain additional funding when needed; and
- manufacturing problems.

We have limited experience in conducting clinical trials, and we rely on others to conduct, supervise or monitor some or all aspects of some of our clinical trials. In addition, certain clinical trials for our product candidates may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. Under our 2005 collaboration agreement with Wyeth, Wyeth had the responsibility to conduct some clinical trials, including all trials outside of the United States other than Japan, where Ono has the responsibility for clinical trials. Upon completion of the transition, we will have responsibility for these trials, or will contract with other parties to conduct them. We have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

Uncertainty over the timing of our clinical trials may impair investors' confidence in our ability to develop products and result in our stock price declining.

We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated fines and delays.

We and our products are subject to comprehensive regulation by the FDA and comparable authorities in other countries. These agencies and other entities regulate the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, recordkeeping, advertising, promotion and other aspects of our products. If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences. We cannot guarantee that approvals of proposed products, processes or facilities will be granted on a timely basis, or at all. If we experience delays or failures in obtaining approvals, commercialization of our product candidates will be slowed or stopped. Even if we obtain regulatory approval, the approval may include significant limitations on indicated uses for which the product could be marketed or other significant marketing restrictions.

As a result of termination of the Wyeth collaboration, we will be responsible for complying with these regulations and will be required to develop an appropriate infrastructure to do so, to the extent we are unable to have such tasks performed by one or more business partners.

Our product candidates may not obtain regulatory approvals needed for marketing, and may face challenges after approval.

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

Even if our products receive regulatory approval:

- They might not obtain labeling claims necessary to make the product commercially viable (in general, labeling claims define the medical conditions for which a drug product may be marketed, and are therefore very important to the commercial success of a product), or may be required to carry “black box” or other warnings that adversely affect their commercial success.

- Approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are relatively less financially advantageous to us than approval of greater or different scope, or subject to an FDA-imposed Risk Evaluation and Mitigation Strategy (REMS) that limits the sources from and conditions under which they may be dispensed.

INDEX

- We or our collaborators might be required to undertake post-marketing trials to verify the product's efficacy or safety.

- We, our collaborators or others might identify side effects after the product is on the market.

- Efficacy or safety concerns regarding marketed products 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. For example, in early 2009 the FDA identified a potential RELISTOR safety issue involving gastrointestinal perforation. The agency is continuing to evaluate to determine the need for any regulatory action; the appearance of a drug on this FDA list does not mean that the agency has concluded that the drug has such a risk. These potential consequences may occur whether or not the concerns originate from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not they are scientifically justified.

- We or our collaborators might experience manufacturing problems, which could have the same, similar or other consequences.

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

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

Competing products may adversely affect our products.

We are aware of the following 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, with an indication "to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis." Adolor is also re-evaluating an entry-stage compound for OIC in chronic-pain patients.

- A Sucampo Pharmaceuticals, Inc.-Takeda Pharmaceutical Company Limited collaboration recently announced top-line results of two phase 3 pivotal clinical trials of AMITIZA® (lubiprostone) for opioid-induced bowel dysfunction.

- A Nektar Therapeutics-AstraZeneca PLC collaboration recently announced positive phase 2 results of an oral peripheral mu-opioid receptor antagonist in patients with OIC, and is developing a combination product based on this oral formulation, combining an opioid with its pegylated mu-opioid receptor antagonist. 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. is evaluating an oral mu-opioid receptor antagonist and combination product in phase 1 clinical testing.

- In Europe, Mundipharma International Limited markets TARGIN® (oxycodone/naloxone), a combination of an opioid and systemic opioid antagonist.

Any of these drugs may achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of these competitors may impair our ability to compete effectively in the market.

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

INDEX

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

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

Our business strategy includes entering into collaborations with pharmaceutical and biotechnology companies to develop and commercialize product candidates and technologies. We are pursuing significant collaborations, strategic partnerships or other arrangements to continue worldwide development and commercialization of RELISTOR following expiration of the transition period of the Transition Agreement. We may not be successful in negotiating additional collaborative arrangements. If we do not enter into new collaborative arrangements -- and in any case prior to entering into any such arrangements -- we would have to devote more of our resources to clinical product development and product-launch activities, seeking additional sources of capital, and our cash burn rate would increase or we would need to take steps to reduce our rate of product development. These challenges will be substantial if we are not successful in negotiating new arrangements with respect to the RELISTOR franchise. We cannot assure you that any currently-contemplated or future collaboration or other initiatives for funding our product candidate programs will be successfully concluded.

We are dependent on our patents and other intellectual property rights. The validity, enforceability and commercial value of these rights are highly uncertain.

Our success is dependent in part upon obtaining, maintaining and enforcing patent and other intellectual property rights. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. Accordingly, patent applications owned by or licensed to us may not result in patents being issued. We are aware of others who have patent applications or patents containing claims similar to or overlapping those in our patents and patent applications. We do not expect to know for several years the relative strength or scope of our patent position. Patents that we own or license may not enable us to preclude competitors from commercializing drugs, and consequently may not provide us with any meaningful competitive advantage.

We own or have licenses to several issued patents. The issuance of a patent, however, is not conclusive as to its validity or enforceability, which can be challenged in litigation. Our patents may be successfully challenged. We may incur substantial costs in litigation seeking to uphold the validity of patents or to prevent infringement. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Third parties may also avoid our patents through design innovation.

Most of our product candidates, including RELISTOR, PRO 140 and our PSMA and HCV program products, incorporate to some degree intellectual property licensed from third parties. We can lose the right to patents and other intellectual property licensed to us if the related license agreement is terminated due to a breach by us or otherwise. Our ability, and that of our collaboration partners, to commercialize products incorporating licensed intellectual property would be impaired if the related license agreements were terminated.

The license agreements from which we derive or out-license intellectual property provide for various royalty, milestone and other payment, commercialization, sublicensing, patent prosecution and enforcement, insurance, indemnification and other obligations and rights, and are subject to certain reservations of rights. While we generally have the right to defend and enforce patents licensed by us, either in the first instance or if the licensor chooses not to

do so, we must usually bear the cost of doing so. As a result of the Transition Agreement, we will be required to defend and enforce our RELISTOR patents, an obligation that Wyeth undertook in the 2005 collaboration agreement. With respect to Japan, Ono has certain limited rights to prosecute, maintain and enforce relevant intellectual property. With most of our in-licenses, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under specified circumstances.

We also rely on unpatented technology, trade secrets and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to our technology or disclose our technology, and we may be unable to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. These agreements may, however, not provide effective protection in the event of unauthorized use or disclosure of confidential information.

INDEX

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

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

If we are unable to obtain sufficient quantities of the raw and bulk materials needed to make our products, our product development and commercialization could be slowed or stopped.

We currently obtain supplies of critical raw materials used in production of our product candidates from single sources. We do not have long-term contracts with any of these suppliers. Wyeth during the transition, and thereafter we, may not be able to fulfill manufacturing obligations for RELISTOR, either on our own or through third-party suppliers. Our existing arrangements with suppliers for our other product candidates may not result in the supply of sufficient quantities of our product candidates needed to accomplish our clinical development programs, and we may not have the right or capability to manufacture sufficient quantities of these products to meet our needs if our suppliers are unable or unwilling to do so. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

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

A substantial portion of our revenues to date, albeit decreasing in 2007, 2008 and 2009, has been derived from federal government grants and research contracts. During the years ended December 31, 2006, 2007, 2008 and the nine months ended September 30, 2009, we generated revenues from awards made to us by the NIH between 2003 and 2009, to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government’s obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them due to their own budgetary constraints. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing awards may be less than those received to date. Therefore, we will need to provide funding on our own or obtain other funding. In particular, we cannot assure you that any currently-contemplated or future efforts to obtain funding for our product candidate programs through government grants or contracts will be successful, or that any such arrangements which we do conclude will supply us with sufficient funds to complete our development programs without providing additional funding on our own or obtaining other funding.

We are exposed to product liability claims, and in the future we may not be able to obtain insurance against these claims at a reasonable cost or at all.

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected. Pursuant to the Transition Agreement, we will assume responsibility for product liability risks arising from marketing and sales of RELISTOR, which Wyeth had borne under our 2005 collaboration.

Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all. We have obtained product liability insurance in the amount of $10.0 million per occurrence, subject to a deductible and a $10.0 million annual aggregate limitation. Where local statutory requirements exceed the limits of our existing insurance or where local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. Our present insurance coverage may not be adequate to cover claims brought against us. Some of our license and other agreements require us to obtain product liability insurance. Adequate insurance coverage may not be available to us at a reasonable cost in the future.

INDEX

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

Our stock price has a history of significant volatility. Between January 1, 2007 and September 30, 2009, our stock price has ranged from $4.33 to $30.31 per share. Between October 1, 2009 and November 4, 2009, it has ranged from $3.72 to $5.48 per share. Historically, our stock price has fluctuated through an even greater range. At times, our stock price has been volatile even in the absence of significant news or developments relating to us. The stock prices of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years, and current financial and market conditions have resulted in widespread pressures on securities of issuers throughout the world economy. Factors that may have a significant impact on the market price of our common stock include:

- the results of clinical trials and pre-clinical studies involving our products or those of our competitors;
- changes in the status of any of our drug development programs, including delays in clinical trials or program terminations;
- developments regarding our efforts to achieve marketing approval for our products;
- developments in our relationships with Wyeth, 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; and
- general market conditions.

Purchases of our common shares pursuant to our share repurchase program may, depending on their timing, volume and form, result in our stock price to be higher than it would be in the absence of such purchases. If purchases under the program are discontinued, our stock price may fall.

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

At September 30, 2009, our directors and executive officers and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately one-fifth of our outstanding shares of common stock.

At that date, our five largest stockholders, excluding our directors and executive officers and stockholders affiliated with Tudor, beneficially own or control in the aggregate approximately 45% of our outstanding shares. Our directors and executive officers and Tudor-related stockholders, should they choose to act together, could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could have the effect of delaying or preventing a change in control of us and, consequently, could adversely affect the market price of our common stock. Other significant but unrelated stockholders could also exert influence in such matters.

INDEX

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

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

Item 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

INDEX

SIGNATURES

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

PROGENICS PHARMACEUTICALS, INC.

Date: November 9, 2009

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