PROGENICS PHARMACEUTICALS INC
Form 10-Q
November 09, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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, 2011
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 x 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 2, 2011 there were 33,762,677 shares of common stock, par value $.0013 per share, of the registrant outstanding.

PROGENICS PHARMACEUTICALS, INC.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

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

	September 30, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 77,998	$ 47,918
Accounts receivable	2,512	2,283
Other current assets	815	1,801
Total current assets	81,325	52,002
Auction rate securities	3,424	3,608
Fixed assets, at cost, net of accumulated depreciation and amortization	4,439	5,878
Other assets	200	1,250
Total assets	$ 89,388	$ 62,738
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,881	$ 9,683
Deferred revenue – current	204	-
Other current liabilities	115	112
Total current liabilities	7,200	9,795
Deferred revenue – long term	213	-
Other liabilities	1,595	1,635
Total liabilities	9,008	11,430
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $.001 par value; 20,000,000 shares authorized; issued and outstanding – none	-	-
Common stock, $.0013 par value; 80,000,000 shares authorized; issued –33,957,003 in 2011 and 33,325,802 in 2010	44	43
Additional paid-in capital	461,281	453,353
Accumulated deficit	(377,928)	(399,055)
Accumulated other comprehensive loss	(276)	(292)
Treasury stock, at cost (200,000 shares in 2011 and 2010)	(2,741)	(2,741)
Total stockholders' equity	80,380	51,308
Total liabilities and stockholders' equity	$ 89,388	$ 62,738

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Collaboration revenue	$ 2,855	$ 82	$ 76,398	$ 1,175
Royalty income	1,240	620	1,767	1,826
Research grants	1,681	1,234	4,346	2,667
Other revenues	28	31	88	127
Total revenues	5,804	1,967	82,599	5,795
Expenses:				
Research and development	12,406	12,967	44,887	35,518
License fees – research and development	114	110	566	1,217
General and administrative	4,064	5,414	14,213	17,568
Royalty expense	147	62	274	182
Depreciation and amortization	520	532	1,581	2,283
Total expenses	17,251	19,085	61,521	56,768
Operating income (loss)	(11,447)	(17,118)	21,078	(50,973)
Other income:				
Interest income	15	17	49	48
Total other income	15	17	49	48
Net income (loss)	$ (11,432)	$ (17,101)	$ 21,127	$ (50,925)
Net income (loss) per share - basic	$ (0.34)	$ (0.52)	$ 0.63	$ (1.57)
Weighted-average shares - basic	33,710	32,814	33,501	32,444
Net income (loss) per share - diluted	$ (0.34)	$ (0.52)	$ 0.63	$ (1.57)
Weighted-average shares - diluted	33,710	32,814	33,664	32,444

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

(amounts in thousands)
(Unaudited)

	Common Stock		Additional		Accumulated Other Comprehensive	Treasury Stock		
	Shares	Amount	Paid-In Capital	Accumulated Deficit	Income (Loss)	Shares	Amount	Total
Balance at December 31, 2010	33,326	$ 43	$ 453,353	$ (399,055)	$ (292)	(200)	$ (2,741)	$ 51,308
Comprehensive income:								
Net income	-	-	-	21,127	-	-	-	21,127
Net change in unrealized loss on auction rate securities	-	-	-	-	16	-	-	16
Total comprehensive income								21,143
Compensation expenses for share-based payment arrangements	-	-	4,695	-	-	-	-	4,695
Issuance of restricted stock, net of forfeitures	(34)	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	665	1	3,233	-	-	-	-	3,234
Balance at September 30, 2011	33,957	$ 44	$ 461,281	$ (377,928)	$ (276)	(200)	$ (2,741)	$ 80,380

	Common Stock		Additional			Treasury Stock		

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

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net income (loss)	$ 21,127	$ (50,925)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,581	2,283
Expenses for share-based compensation awards	4,695	7,726
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(229)	3,045
Decrease (increase) in other current assets	986	(458)
Decrease in other assets	1,050	730
(Decrease) increase in accounts payable and accrued expenses	(2,802)	812
Increase in deferred revenue – current and long term	417	-
(Decrease) increase in other liabilities	(37)	1,718
Net cash provided by (used in) operating activities	26,788	(35,069)
Cash flows from investing activities:		
Capital expenditures	(142)	(2,127)
Sales/maturities of marketable securities	200	1,700
Net cash provided by (used in) investing activities	58	(427)
Cash flows from financing activities:		
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	3,234	2,987
Net cash provided by financing activities	3,234	2,987
Net increase (decrease) in cash and cash equivalents	30,080	(32,509)
Cash and cash equivalents at beginning of period	47,918	90,903
Cash and cash equivalents at end of period	$ 77,998	$ 58,394

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

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PROGENICS PHARMACEUTICALS, INC.

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

1. Interim Financial Statements

Progenics 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. In recent years, our principal programs have been directed toward gastroenterology, oncology and virology, including development and regulatory approval of our first commercial product, RELISTOR® (methylnaltrexone bromide) subcutaneous injection, a first-in-class therapy for opioid-induced constipation which we have licensed to Salix Pharmaceuticals, Inc. worldwide except in Japan, where Ono Pharmaceutical Co., Ltd. is developing the subcutaneous formulation of the drug.

We have reoriented the Company's research and development focus on oncology. We are allocating additional financial and personnel resources to our PSMA ADC program, where we are conducting a phase 1 clinical trial of a proprietary, fully human monoclonal antibody-drug conjugate (ADC) directed against prostate-specific membrane antigen (PSMA) for the treatment of prostate cancer, and our pre-clinical development work on novel multiplex phosphoinositide 3-kinase (PI3K) inhibitors for the treatment of cancer, and are seeking to in-license or acquire complementary opportunities in the oncology field. The Company is looking to out-license existing programs not within its oncology focus.

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

RELISTOR subcutaneous injection has been approved for sale in the United States since 2008 and is approved in over 50 countries worldwide, including the European Union, Canada and Australia. Marketing applications are pending elsewhere throughout the world. In addition to the FDA-approved indication for advanced illness patients, a supplemental New Drug Application (sNDA) for subcutaneous RELISTOR in non-cancer pain patients, submitted to the FDA earlier this year, has been accepted for filing with an action date under the U.S. Prescription Drug User Fee Act (PDUFA) of April 27, 2012, and we expect Salix to announce top-line data from the ongoing phase 3 trial of oral methylnaltrexone in non-cancer pain patients late this year or in early 2012.

In connection with the Salix License Agreement, we have received through September 30, 2011, $60.2 million upfront cash payments and are eligible to receive (i) up to $40.0 million upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients, (ii) up to $50.0 million upon U.S. marketing approval of an oral formulation of RELISTOR, (iii) up to $200.0 million of commercialization milestone payments upon achievement of specified U.S. sales targets, (iv) royalties ranging from 15 to 19 percent of net sales by Salix and its affiliates, and (v) 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Salix receives from sublicensees outside the U.S. In the event that either marketing approval is subject to a Black Box Warning or Risk Evaluation and Mitigation Strategy (REMS), payment of a portion of the milestone amount would be deferred, and subject, to achievement of the first commercialization milestone.

RELISTOR was previously developed and commercialized by Progenics and Wyeth Pharmaceuticals, now a Pfizer Inc. subsidiary. Under our 2009 Transition Agreement, Wyeth continued to distribute RELISTOR in the U.S. until Salix assumed that responsibility on April 1, 2011. Salix, Progenics and Wyeth have transitioned European and other marketing authorizations and are transitioning additional ex-U.S. and ex-Japan commercialization on a

country-by-country basis. Salix is continuing its efforts to secure a distribution partner for RELISTOR in the European territory and has granted a license to Link Medical Products Pty Limited for distribution in Australia, New Zealand, South Africa and markets in Asia.

Wyeth is providing financial resources to us and Salix of approximately $9.5 million, of which we have recognized $1.6 million for the nine months ended September 30, 2011 and $1.2 million in 2010, for development of a multi-dose pen for subcutaneous RELISTOR; $6.7 million remains available to support development activities assumed by Salix. Reimbursement from such financial support to us has been reported as collaboration revenue through September 30, 2011 under the Transition Agreement.

Financial and Funding. The Salix License Agreement entitles us to upfront, milestone and sales related (royalty and revenue sharing) payments, as well as reimbursement by Salix for full-time equivalents (FTE) and third-party development expenses incurred and paid at its direction after February 3, 2011. We recorded payments received from Salix as deferred revenue during the periods in which transfer activities were ongoing or future development work was being planned; as a result, the $60.0 million upfront payment received in February was recorded as deferred revenue as of March 31, 2011. Of this amount, we recognized $59.5 million and $0.1 million in collaboration revenue during the second and third quarters of 2011, respectively.

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PROGENICS PHARMACEUTICALS, INC.

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

For the three and nine months ended September 30, 2011, we incurred approximately $3.5 million and $22.2 million, respectively, of RELISTOR related expenses for which we have received reimbursements from Salix and Wyeth totaling $14.7 million through September 30, 2011, and in respect of which we expect to receive $0.7 million during the fourth quarter. Now that we and Salix have agreed upon a RELISTOR development plan, we record paid expenses which are eligible for reimbursement from Salix in collaboration revenue. RELISTOR expenses and reimbursements have declined substantially in the second half of 2011 since Salix has assumed direct responsibility for expenses under third-party contracts we have assigned to it, and we continue to perform limited development tasks.

At September 30, 2011, we held $78.0 million in cash and cash equivalents, a $4.4 million decrease from the second quarter-end, and a $30.1 million increase from year-end 2010. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We may require additional funding in the future, and if we are unable to enter into favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend our remaining operations. At September 30, 2011, cash, cash equivalents and auction rate securities decreased $4.5 million to $81.4 million from $85.9 million at June 30, 2011.

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, 2011.

Our interim Consolidated Financial Statements included in this report have been prepared in accordance with applicable presentation requirements, and accordingly do not include all information and disclosures necessary for a presentation of our financial position, results of operations and cash flows in conformity with accounting principles generally accepted in the United States of America (“GAAP”). In the opinion of management, these financial statements reflect all adjustments, consisting primarily of normal recurring accruals necessary for a fair statement of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. Our interim financial statements should be read in conjunction with the financial statements and notes thereto contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. The year-end consolidated balance sheet data in these financial statements were derived from audited financial statements, but do not include all disclosures required by GAAP.

2. Revenue Recognition

We recognize revenue from all sources based on the provisions of the U.S. SEC’s Staff Accounting Bulletin No. 104 and ASC 605 Revenue Recognition. In October 2009, the FASB updated ASC 605 Revenue Recognition by specifying how to separate deliverables in multiple-deliverable arrangements, and how to measure and allocate arrangement consideration to one or more units of accounting. Under ASC 605, the delivered item(s) are separate units of accounting, provided (i) the delivered item(s) have value to a collaborator on a stand-alone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We adopted this update on January 1, 2011. In April 2010, the FASB issued a separate update to ASC 605 which provides guidance on the criteria that should be met when determining whether the milestone method of revenue recognition is appropriate. This method is effective on a prospective basis for milestones achieved after January 1, 2011. We did not achieve any milestones between that date and September 30, 2011; after a milestone is achieved, we will determine whether or not to make a

policy election to adopt the milestone method.

There have been no other changes to our revenue recognition accounting policies as of and for the nine months ended September 30, 2011, which policies are disclosed in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010.

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PROGENICS PHARMACEUTICALS, INC.

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

License Agreement with Salix – February 2011

Under our license agreement, as described above, Salix is responsible for continuing development and commercialization of subcutaneous RELISTOR, including completing clinical development necessary to support regulatory marketing approvals for potential new indications and formulations. We have granted Salix an exclusive license of relevant know-how, patent rights and technology, assigned relevant third-party contracts, and performed substantially all of our other transition-related activities as of June 30, 2011. During the second quarter of 2011, we and Salix completed a number of tasks involved in enabling Salix to distribute RELISTOR in the U.S. and the European Union, as well as clinical and regulatory development related activities, and have agreed with Salix on research and development services we are to perform at Salix's direction. We have not performed any significant research and development activities during the third quarter.

In consideration of the $60.0 million upfront payment from Salix, we are responsible for delivering to Salix an exclusive license of relevant know-how, patent rights and technology and serving on joint committees provided for in the License Agreement. These deliverables, which have stand-alone value and represent separate units of accounting, include (i) the exclusive license which was delivered for revenue recognition purposes during the 2011 second quarter, (ii) performing reimbursable development services at Salix's direction during the 2011 second quarter, the period in which we and Salix finalized the development plan, and (iii) joint committee services, which we expect to perform through 2013. We determined that the license has stand-alone value as the license was delivered to Salix for revenue recognition purposes in the second quarter of 2011 and Salix is responsible for continuing research and development.

We developed a best estimate of selling price for each deliverable as vendor-specific objective evidence and third-party evidence was not available. We allocated the best estimate of selling price, on a relative basis, to each of the three units of accounting as the $60.0 million upfront payment was the only payment from Salix which was fixed and determinable at the inception of the arrangement. As a result, $58.4 million, $1.1 million and $0.5 million was allocated to the license, reimbursable development services and our participation in the joint committees as provided in the License Agreement, respectively. We recognized $58.4 million for the license and relevant know-how, patent rights and technology and $1.1 million for the reimbursable development services, respectively, during the second quarter of 2011, the period in which we delivered these items and performed the development services.

During the third quarter of 2011, we performed joint committee services which resulted in the recognition of $0.1 million and the remaining $0.4 million for these services is recognized in collaboration revenue as such activities are performed in the future. In addition, we received $0.2 million during the third quarter in respect of Salix ex-U.S. sublicensee revenue, which was recognized in collaboration revenue.

Transition Agreement with Wyeth – October 2009

Under the Transition Agreement, Wyeth's license of Progenics' technology under the original 2005 collaboration was terminated except as necessary for performance of its obligations during the transition period, and Wyeth returned the rights to RELISTOR that we had previously granted. During the transition, Wyeth was obligated to pay all costs of commercialization of subcutaneous RELISTOR, including manufacturing costs, and retained all proceeds from its sale of the products, subject to royalties that were due to us for sales made prior to September 30, 2010. Decisions with respect to commercialization of the product during the transition period were made solely by Wyeth. As of the beginning of the fourth quarter of 2011, Salix has assumed substantially all of Wyeth's remaining ex-U.S. development

and commercialization activities for RELISTOR worldwide ex-Japan.

Ono Agreement – October 2008

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting clinical development necessary to support regulatory marketing approval. Ono will own the filings and approvals related to subcutaneous RELISTOR in Japan. 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, at its expense payable at the time we perform such services. Revenue earned from activities we perform for Ono is recorded in collaboration revenue.

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PROGENICS PHARMACEUTICALS, INC.

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

Collaboration Revenue

During the three and nine months ended September 30, 2011, we recognized revenue of $2,854 and $74,738, respectively ($71,884 in the second quarter) under the Salix License Agreement; $0 and $1,630, respectively, under the Wyeth Transition Agreement; and $1 and $30, respectively, under the Ono Agreement. Of the $60.0 million in deferred revenue as of March 31, 2011, we have recognized $0.1 million and $59.6 million in collaboration revenue during the three and nine months ended September 30, 2011, as described above. As of September 30, 2011, $204 and $213 is recorded in deferred revenue – current and long-term, respectively, which is attributable to joint committee services remaining to be completed under the License Agreement and is recognized in collaboration revenue as such activities are performed in the future, as described above.

RELISTOR Royalties

Under the terms of the Wyeth transition, no royalties have been due to us during 2011 in respect of RELISTOR sales reported by Wyeth. During the three and nine months ended September 30, 2011, we recognized royalty income of $1,240 and $1,767, respectively, based on net U.S. sales of RELISTOR reported by Salix. During the three and nine months ended September 30, 2010, we recognized royalty income of $620 and $1,826, respectively, based on net sales of subcutaneous RELISTOR reported by Wyeth. We incurred $147 and $274, respectively, of royalty expenses during the three and nine months ended September 30, 2011 and $62 and $182, respectively during the three and nine months ended September 30, 2010.

3. Net Income (Loss) Per Share

Our basic net income (loss) per share amounts have been computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period. For the nine months ended September 30, 2011, we reported net income, and the computation of diluted earnings per share is based upon the weighted-average number of our common shares and dilutive effect, determined using the treasury stock method, of potential common shares outstanding. For the three months ended September 30, 2011 and for the three and nine months ended September 30, 2010, we reported net losses and, therefore, potential common shares are not included since inclusion would have been anti-dilutive. The calculations of net income (loss) per share, basic and diluted, for these periods are as follows:

	Net Income (Loss) (Numerator)	Weighted Average Common Shares (Denominator)	Per Share Amount
Three months ended September 30, 2011			
Basic and diluted	$ (11,432)	33,710	$ (0.34)
Nine months ended September 30, 2011			
Basic	$ 21,127	33,501	$ 0.63
	-	142	

Dilutive effect of stock options				
Dilutive effect of restricted stock		-	21	
Diluted	$	21,127	33,664	$ 0.63
Three months ended September 30, 2010				
Basic and diluted	$	(17,101)	32,814	$ (0.52)
Nine months ended September 30, 2010				
Basic and diluted	$	(50,925)	32,444	$ (1.57)

For the three and nine months ended September 30, 2011 and 2010, anti-dilutive common shares excluded from diluted per share amounts consist of the following:

	Three Months Ended September 30,			
	2011		2010	
	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price
Stock options	6,186	$ 12.65	5,377	$ 14.34
Restricted stock	9		11	
Total	6,195		5,388	

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PROGENICS PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,			
	2011		2010	
	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price
Stock options	4,126	$ 15.78	4,949	$ 15.52
Restricted stock	-		34	
Total	4,126		4,983	

4. Fair Value Measurements and Marketable Securities

Our available-for-sale investments consist of money market funds and auction rate securities and are recorded at fair value in the accompanying Consolidated Balance Sheets in accordance with ASC 320 Investments – Debt and Equity Securities. The change in the fair value of these investments is recorded as a component of other comprehensive loss (see Note 2. Summary of Significant Accounting Policies - Fair Value Measurements in the notes to consolidated financial statements included in our 2010 Annual Report on Form 10-K).

The following tables present our available-for-sale investments measured at fair value on a recurring basis, summarized by valuation hierarchy, as of September 30, 2011 and December 31, 2010:

		Fair Value Measurements at September 30, 2011		
	Balance at September 30, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 70,954	$ 70,954	$ -	$ -
Auction rate securities	3,424	-	-	3,424
Total	$ 74,378	$ 70,954	$ -	$ 3,424

		Fair Value Measurements at December 31, 2010		
	Balance at December 31, 2010	Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

		Assets (Level 1)		
Money market funds	$ 43,958	$ 43,958	$ -	$ -
Auction rate securities	3,608	-	-	3,608
Total	$ 47,566	$ 43,958	$ -	$ 3,608

At September 30, 2011 we hold $3.4 million (4.6% of total assets measured at fair value) in auction rate securities which are classified as Level 3. The fair value of these securities includes $2.5 million of U.S. government subsidized securities collateralized by student loan obligations and $0.9 million of investment company perpetual preferred stock. We will not realize cash in respect of the principal amount of these securities until the issuer calls or restructures the security, the security reaches any scheduled maturity and is paid, or a buyer outside the auction process emerges. As of September 30, 2011, we have received all scheduled interest payments on these securities, which, in the event of auction failure, are reset according to contractual terms in the governing instruments.

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PROGENICS PHARMACEUTICALS, INC.

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

The valuation of auction rate securities 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. In re-evaluating the valuation of these securities as of September 30, 2011, the temporary impairment amount decreased to $276 at September 30, 2011 from $292 at December 31, 2010. 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 Consolidated Balance Sheets. 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. 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 auction rate securities), the following table summarizes the activities for the three and nine months ended September 30, 2011 and 2010:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended September 30,	
Description	2011	2010
Balance at beginning of period	$ 3,516	$ 3,608
Transfers into Level 3	-	-
Total realized/unrealized gains (losses)		
Included in net loss	-	-
Included in comprehensive loss (1)	8	-
Settlements	(100)	-
Balance at end of period	$ 3,424	$ 3,608
(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) For the Nine Months Ended September 30,	
Description	2011	2010

Balance at beginning of period	$ 3,608	$ 3,792
Transfers into Level 3	-	-
Total realized/unrealized gains (losses)		
Included in net loss	-	-
Included in comprehensive loss (1)	16	16
Settlements	(200)	(200)
Balance at end of period	$ 3,424	$ 3,608
(1) Total amount of unrealized gains (losses) for the period included in other comprehensive loss attributable to the change in fair market value of related assets still held at the reporting date	$ -	$ -

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PROGENICS PHARMACEUTICALS, INC.

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

5. Accounts Receivable

	September 30, 2011	December 31, 2010
Collaborators	$ 709	$ 1,811
Royalties	1,240	-
National Institutes of Health	538	468
Other	25	4
Total	$ 2,512	$ 2,283

6. Accounts Payable and Accrued Expenses

	September 30, 2011	December 31, 2010
Accrued consulting and clinical trial costs	$ 2,056	$ 6,125
Accrued payroll and related costs	3,596	1,725
Legal and professional fees	530	1,116
Accounts payable	523	658
Other	176	59
Total	$ 6,881	$ 9,683

7. Restructuring

As part of the reorientation of our research and development focus on oncology, in the third quarter we reduced headcount resulting in a restructuring accrual of $1.1 million which will be paid during the period from October 2011 through August 2012. This accrual consists of:

	For the Three and Nine Months Ended September 30, 2011
Severance and related benefits	$ 1,064
Total	$ 1,064

Activity in the third quarter restructuring accrual, which is included in accounts payable and accrued expenses in our Consolidated Balance Sheets and research and development and general and administrative expenses in the Consolidated Statements of Operations, is specified below. We expect to incur additional employee termination benefit expense accruals related to this restructuring upon completion of arrangements finalized after third-quarter end.

	Severance and related benefits
Initial expense accrual	$ 1,064
Cash payments	-
Balance at September 30, 2011	$ 1,064

8. 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, 2011.

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PROGENICS PHARMACEUTICALS, INC.

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

9. Accounting Standards

In June 2011, the FASB issued ASU No. 2011-05, which requires that comprehensive income and the related components be presented in a single continuous statement or in two separate but consecutive statements. The ASU, which is applied retrospectively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We are currently evaluating the effect this ASU will have on our consolidated financial statements.

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

Note Regarding Forward-Looking Statements

This document and other public statements we make may contain 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.

Additional information concerning Progenics and its business may be available in press releases or other public announcements and public filings made after this Report.

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. In recent years, our principal programs have been directed toward gastroenterology, oncology and virology, including development and regulatory approval of our first commercial product, RELISTOR® (methylnaltrexone bromide) subcutaneous injection, a first-in-class therapy for opioid-induced constipation which we have licensed to Salix Pharmaceuticals, Inc. worldwide except in Japan, where Ono Pharmaceutical Co., Ltd. is developing the subcutaneous formulation of the drug.

We have reoriented the Company’s research and development focus on oncology. We are allocating additional financial and personnel resources to our PSMA ADC program, where we are conducting a phase 1 clinical trial of a proprietary, fully human monoclonal ADC directed against PSMA for the treatment of prostate cancer, and our pre-clinical development work on novel multiplex PI3K inhibitors for the treatment of cancer, and are seeking to in-license or acquire complementary opportunities in the oncology field. The Company is looking to out-license existing programs not within its oncology focus.

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Progenics commenced principal operations in 1988, became publicly traded in 1997 and throughout has been engaged primarily in research and development efforts, establishing corporate collaborations and related activities.

In re-partnering our first commercial product, RELISTOR, with Salix Pharmaceuticals we have received through September 30, 2011, $60.2 million upfront cash payments and are eligible to receive (i) up to $40.0 million upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients, (ii) up to $50.0 million upon U.S. marketing approval of an oral formulation of RELISTOR, (iii) up to $200.0 million of commercialization milestone payments upon achievement of specified U.S. sales targets, (iv) royalties ranging from 15 to 19 percent of net sales by Salix and its affiliates, and (v) 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Salix receives from sublicensees outside the U.S. In the event that either marketing approval is subject to a Black Box Warning or Risk Evaluation and Mitigation Strategy (REMS), payment of a portion of the milestone amount would be deferred, and subject, to achievement of the first commercialization milestone.

During the three and nine months ended September 30, 2011, our sources of revenue consisted of (i) $0.1 million and $59.6 million, respectively, pertaining to the $60.0 million upfront payment from Salix, (ii) $0.2 million received in the third quarter in respect of Salix ex-U.S. sublicensee revenue, and (iii) $5.5 million and $22.8 million, respectively, from Salix, Wyeth, National Institutes of Health (NIH) and other collaboration reimbursements. In June 2008, we began recognizing royalty income from net sales reported by Wyeth of subcutaneous RELISTOR. To date, our own product sales have consisted solely of limited revenues from the sale of research reagents and we expect that sales will not significantly increase over current levels in the near future. We expect revenue from the NIH to decline in the future to the extent we out-license existing NIH-funded programs not in the oncology area.

A majority of our expenditures to date have been for research and development activities. For the three months ended September 30, 2011, our expenses for the RELISTOR and HIV research programs decreased to $3.5 million and $1.1 million, respectively, compared to $6.0 million and $1.3 million, respectively, for the same period in 2010. In this period expenses for our Cancer research program increased to $5.4 million compared to $3.5 million for the same period in 2010.

For the nine months ended September 30, 2011, our expenses for the RELISTOR research program increased to $22.2 million, compared to $13.7 million for the same period in 2010, primarily due to expenses related to the phase 3 study of oral methylnaltrexone and the submission of the sNDA for subcutaneous RELISTOR for non-cancer pain patients. Of this $22.2 million in RELISTOR expenses, we have received reimbursements totaling $13.9 million from Salix and $0.8 million from Wyeth through September 30, 2011, and expect to receive an additional $0.7 million during the fourth quarter. Expenses for our Cancer research program increased to $12.7 million for the nine months of 2011 compared to $11.7 million for the same period in 2010, and expenses for the HIV research program decreased to $3.5 million for the nine months of 2011 compared to $4.6 million for the same period in 2010. We expect future expenses related to research and development for which we receive reimbursement from the NIH to decline to the extent we out-license these programs.

Under the Salix License Agreement, we are reimbursed for Salix approved full-time equivalents (FTE) and third-party expenses incurred and paid by us after February 3, 2011. We recorded payments we received from Salix as deferred revenue during the periods in which transfer activities were ongoing or future development work was being planned. For the three and nine months ended September 30, 2011, we incurred approximately $3.5 million and $22.2 million, respectively, of RELISTOR related expenses for which we have received reimbursements from Salix and Wyeth totaling $14.7 million through September 30, 2011, and in respect of which we expect to receive $0.7 million during the fourth quarter. As the RELISTOR development plan has been finalized, we now record paid expenses which are eligible for reimbursement in collaboration revenue. We will not be reimbursed by Salix or Wyeth for $6.5 million of

2011 RELISTOR expenses incurred prior to the February Salix license agreement or expenses otherwise not reimbursable under the license or the Wyeth Transition Agreement. We will receive reimbursements for RELISTOR related expenses in the future to the extent we perform development tasks requested by Salix or Ono.

At September 30, 2011, we held $78.0 million in cash and cash equivalents, a $4.4 million decrease from $82.4 million at June 30, 2011, and a $30.1 million increase from $47.9 million at December 31, 2010. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We may require additional funding in the future, and if we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend our remaining operations. At September 30, 2011, cash, cash equivalents and auction rate securities decreased $4.5 million to $81.4 million from $85.9 million at June 30, 2011.

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Prior to the Salix license, RELISTOR was developed and commercialized by Progenics and Wyeth. Under our Transition Agreement ending that collaboration, Wyeth continued to distribute RELISTOR in the U.S. until Salix assumed that responsibility on April 1, 2011. Salix, Progenics and Wyeth have transitioned European and other marketing authorizations and are transitioning additional ex-U.S. and ex-Japan commercialization on a country-by-country basis. Salix is continuing its efforts to secure a distribution partner for RELISTOR in the European territory and has granted a license to Link Medical Products Pty Limited for distribution in Australia, New Zealand, South Africa and markets in Asia.

Wyeth is providing financial resources to us and Salix of approximately $9.5 million, of which we have recognized $1.6 million for the nine months ended September 30, 2011 and $1.2 million in 2010, for development of a multi-dose pen for subcutaneous RELISTOR; $6.7 million remains available to support development activities assumed by Salix. Reimbursement from this financial support to us has been reported in collaboration revenue through September 30, 2011, under the Transition Agreement.

We have received U.S., E.U. and Canadian approvals to market RELISTOR in pre-filled syringes, which are designed to ease preparation and administration for patients and caregivers, and expect Salix to launch that product early next year.

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

Royalty and milestone payments will depend on success in development and commercialization of RELISTOR, which in turn is dependent on many factors, such as the actions of Salix and its sublicensees and Ono, decisions by the FDA and other regulatory bodies, the outcome of clinical and other testing of RELISTOR, and our own efforts. Most of these matters are substantially outside our control and none can be predicted with certainty. We expect to incur additional employee termination benefit expense accruals related to the restructuring upon completion of arrangements finalized after third-quarter end.

Results of Operations (amounts in thousands unless otherwise noted)

Revenues:

Our sources of revenue during the three and nine months ended September 30, 2011 and 2010 included the License Agreement with Salix, Transition Agreement with Wyeth, License Agreement with Ono, research grants from the NIH and, to a small extent, sale of research reagents.

	Three Months Ended September 30,			Nine Months Ended September 30,		
Sources of Revenue	2011	2010	Percent Change	2011	2010	Percent Change

Collaboration revenue	$ 2,855	$ 82	3,382 %	$ 76,398	$ 1,175	6,402 %
Royalty income	1,240	620	100 %	1,767	1,826	(3 %)
Research grants	1,681	1,234	36 %	4,346	2,667	63 %
Other revenues	28	31	(10 %)	88	127	(31 %)
Total	$ 5,804	$ 1,967	195 %	$ 82,599	$ 5,795	1,325 %

Collaboration revenue:

Salix License Agreement. During the three and nine months ended September 30, 2011, we recognized $2,854 and $74,738, respectively, of revenue from Salix, which includes $51 and $59,583, respectively, of previously deferred revenue in respect of the $60.0 million upfront payment under the License Agreement, $225 and $225, respectively, in respect of Salix ex-U.S. sublicensee revenue and $2,578 and $14,930, respectively, as reimbursement of our expenses, including $2,172 of manufacturing supplies, in accordance with the License Agreement. Of the $74.7 million recognized to date, we received $73.7 million in cash during the first nine months of 2011 and expect to receive the remaining $0.7 million during the fourth quarter. As of September 30, 2011, $0.2 million and $0.2 million are recorded in deferred revenue – current and long-term, respectively, representing joint committee activities that remain to be completed.

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Wyeth Collaboration. During the three months ended September 30, 2011 and 2010, we recognized $0 and $55, respectively, and during the nine months ended September 30, 2011 and 2010, we recognized $1,630 and $1,145, respectively, of revenue from Wyeth, as reimbursement of our expenses under the 2009 Transition Agreement.

Ono License Agreement. During the three months ended September 30, 2011 and 2010, we recognized $1 and $27, respectively, and during the nine months ended September 30, 2011 and 2010, we recognized $30 and $30, respectively, of reimbursements as revenue for activities requested by Ono.

Royalty income. During the three months ended September 30, 2011 and 2010, we recognized $1,240 and $620, respectively, and during the nine months ended September 30, 2011 and 2010, we recognized $1,767 and $1,826, respectively, of royalty income from net sales of subcutaneous RELISTOR reported to us by our collaborators. No royalties were due to us during the first quarter of 2011 and royalties for the second and third quarters of 2011 are attributable only to U.S. net sales, the basis for 2011 royalty income, by Salix.

RELISTOR Net Sales by Collaborators (in millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
U.S.	$8.2	$ 2.4	$ 13.5	$ 7.2
Ex-U.S.	1.5	1.7	4.7	5.0
Global	$9.7	$ 4.1	$ 18.2	$ 12.2

Research grants. Revenues from direct and indirect research grants from the NIH increased to $1,681 for the three months ended September 30, 2011 from $1,234 for the three months ended September 30, 2010 and increased to $4,346 for the nine months ended September 30, 2011 from $2,667 for the nine months ended September 30, 2010. The increase in grant revenue resulted from new grant awards and higher reimbursable expenses in 2011 than in 2010. We expect revenue from the NIH to decline in the future to the extent we out-license existing NIH-funded programs not in the oncology area.

Other revenues, primarily from orders for research reagents, decreased to $28 for the three months ended September 30, 2011 from $31 for the same period in 2010 and decreased to $88 for the nine months ended September 30, 2011 from $127 for the same period in 2010.

Expenses:

Research and Development Expenses include scientific labor, clinical trial costs, supplies, product manufacturing costs, consulting, license fees, royalty payments and other operating expenses. Research and development expenses decreased to $12,667 for the three months ended September 30, 2011 from $13,139 for the same period of 2010 and increased to $45,727 for the nine months ended September 30, 2011 from $36,917 for the same period of 2010, as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change

Salaries and benefits	$ 5,216	$ 4,354	20%	$ 14,868	$ 14,202	5%

Three Months: Salaries and benefits increased due to $0.9 million in accrued severance expense related to third quarter headcount reduction and higher accrued bonus expense, partially offset by a decrease in salary expenses due to a decline in average headcount to 102 from 135 for the three months ended September 30, 2011 and 2010, respectively, in the research and development departments.

Nine Months: Salaries and benefits increased due to $0.9 million in accrued severance expense related to third quarter headcount reduction and higher accrued bonus expense, partially offset by a decrease in salary expenses due to a decline in average headcount to 111 from 142 for the nine months ended September 30, 2011 and 2010, respectively, in the research and development departments.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Share-based compensation	$ 1,243	$ 1,436	(13%)	$ 3,423	$ 4,086	(16%)

Three Months: Share-based compensation decreased for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 due to lower restricted stock and employee stock purchase plan expenses, partially offset by higher stock option plan expenses.

Nine Months: Share-based compensation decreased for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 due to lower restricted stock and employee stock purchase plan expenses, partially offset by higher stock option plan expenses.

For the nine months ended September 30, 2011, share-based compensation included restricted stock and option plan expenses from (i) accelerated vesting of outstanding awards to non-management employees in connection with a change in program eligibility and termination of the Company’s employee stock purchase plans (which we expect to result in a decline in future share-based compensation), and (ii) a shift in headcount from general and administrative departments to research and development.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Clinical trial costs	$ 413	$ 2,108	(80%)	$ 9,685	$ 3,003	223%

Three Months: Clinical trial costs decreased primarily due to lower expenses for (i) RELISTOR ($1,591), from decreased clinical trial expenses including activities related to the oral methylnaltrexone phase 3 study, (ii) Cancer ($94), and (iii) HIV ($8), all for the three months ended September 30, 2011 compared to the three months ended September 30, 2010.

Nine Months: Clinical trial costs increased primarily due to higher expenses for RELISTOR ($7,297), from increased clinical trial expenses including activities related to the oral methylnaltrexone phase 3 study and regulatory filing fees for the submission of the sNDA for subcutaneous RELISTOR, partially offset by decreases in Cancer ($489) and HIV ($124), all for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Laboratory and manufacturing supplies	$ 2,572	$ 797	223%	$ 3,948	$ 1,764	124%

Three Months: Laboratory and manufacturing supplies increased due to higher expenses for (i) RELISTOR ($1,747), primarily due to purchases of manufacturing supplies on behalf of Salix, (ii) HIV ($32), and (iii) Other projects ($74), partially offset by decrease in Cancer ($78) due to a decrease in expenses for PSMA ADC, all for the three months ended September 30, 2011 compared to the same period in 2010.

Nine Months: Laboratory and manufacturing supplies increased due to higher expenses for (i) RELISTOR ($1,723), primarily due to purchases of manufacturing supplies on behalf of Salix, (ii) Cancer ($297), resulting from an increase in expenses for PSMA ADC, and (iii) Other projects ($197), partially offset by a decrease in HIV ($33), all for the nine months ended September 30, 2011 compared to the same period in 2010.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Contract manufacturing and subcontractors	$ 1,009	$ 1,419	(29%)	$ 5,872	$ 4,495	31%

Three Months: Contract manufacturing and subcontractors decreased due to lower expenses for (i) RELISTOR ($157), (ii) HIV ($61), for HIV Vaccine, (iii) Other ($160) and (iv) Cancer ($32), all for the three months ended September 30, 2011 compared to the same period in 2010.

Nine Months: Contract manufacturing and subcontractors increased due to higher expenses for RELISTOR ($1,009), due to purchases of subcutaneous RELISTOR related products, and HIV ($509), for HIV Vaccine, partially offset by decreases in Cancer ($123), due to lower contract manufacturing expenses for PSMA ADC, and Other ($18), all for the nine months ended September 30, 2011 compared to the same period in 2010.

These expenses are related to the conduct of clinical trials, including manufacture by third parties of drug materials, testing, analysis, formulation and toxicology services, and vary as the timing and level of such services are required.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Consultants	$ 164	$ 992	(83%)	$ 1,143	$ 1,793	(36%)

Three Months: Consultants expenses decreased due to lower expenses for RELISTOR ($848), Other projects ($17) and HIV ($2) partially offset by an increase in Cancer ($39), all for the three months ended September 30, 2011 compared to the three months ended September 30, 2010.

Nine Months: Consultants expenses decreased due to lower expenses for RELISTOR ($659), HIV ($38) and Other projects ($15), partially offset by an increase in Cancer ($62), all for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

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,		
	2011	2010	Percent Change	2011	2010	Percent Change
License fees	$ 114	$ 110	4%	$ 566	$ 1,217	(53%)

Three Months: License fees increased for the three months ended September 30, 2011 compared to the three months ended September 30, 2010, due to higher expenses for RELISTOR ($4).

Nine Months: License fees decreased primarily due to lower expenses for HIV ($667), partially offset by higher expenses for RELISTOR ($16), all for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Royalty expense	$ 147	$ 62	137%	$ 274	$ 182	51%

Three Months: We incurred $147 and $62, respectively, of royalty expenses during the three months ended September 30, 2011 and 2010.

Nine Months: We incurred $274 and $182, respectively, of royalty expenses during the nine months ended September 30, 2011 and 2010.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Other operating expenses	$ 1,789	$ 1,861	(4%)	$ 5,948	$ 6,175	(4%)

Three Months: Other operating expenses decreased for the three months ended September 30, 2011 compared to the three months ended September 30, 2010, primarily due to decreases in other operating expenses ($84), travel ($30) and facilities ($17), partially offset by increases in insurance ($39) and rent ($20).

Nine Months: Other operating expenses decreased for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010, primarily due to decreases in rent ($355) and facilities ($112), partially offset by increases in other operating expenses ($147), insurance ($66) and travel ($27).

General and Administrative Expenses decreased to $4,064 for the three months ended September 30, 2011 from $5,414 for the same period of 2010 and decreased to $14,213 for the nine months ended September 30, 2011 from $17,568 for the same period of 2010, as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Salaries and benefits	$ 1,918	$ 1,710	12%	$ 5,748	$ 6,092	(6%)

Three Months: Salaries and benefits increased for the three months ended September 30, 2011 compared to the same period in 2010, due to $0.2 million in accrued severance expense and higher accrued bonus expense, partially offset by a decrease in salary expenses due to a decline in average headcount to 30 from 38, in the general and administrative departments.

Nine Months: Salaries and benefits decreased for the nine months ended September 30, 2011 compared to the same period in 2010, due to a decline in average headcount to 33 from 40, in the general and administrative departments, partially offset by $0.2 million in accrued severance expense and higher accrued bonus expense.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Share-based compensation	$ 179	$ 1,473	(88%)	$ 1,272	$ 3,640	(65%)

Three Months: Share-based compensation decreased due to a decline in stock option, restricted stock and employee stock purchase plans expenses, all for the three months ended September 30, 2011 compared to the three months ended September 30, 2010.

Nine Months: Share-based compensation decreased due to a decline in stock option, restricted stock and employee stock purchase plans expenses, all for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

For the nine months ended September 30, 2011, share-based compensation reflected accelerated vesting in connection with termination of our employee stock purchase plans, as described under research and development expenses, above.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Consulting and professional fees	$ 816	$ 1,252	(35%)	$ 3,636	$ 4,250	(14%)

Three Months: Consulting and professional fees decreased due to lower legal ($306) and legal patent expenses ($222), which were partially offset by higher consultants ($76) and other expenses ($16), all for the three months ended September 30, 2011 compared to the three months ended September 30, 2010.

Nine Months: Consulting and professional fees decreased due to lower legal patent ($750) and legal expenses ($520), which were partially offset by higher consultants ($535), tax accounting ($71) and other expenses ($50), all for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Other operating expenses	$ 1,151	$ 979	18%	$ 3,557	$ 3,586	(1%)

Three Months: Other operating expenses increased due to higher expenses for computer software ($47), taxes ($27), investor relations ($15), rent ($6), and other operating expenses ($88), partially offset by a decrease in recruiting ($11), all for the three months ended September 30, 2011 compared to the same period in 2010.

Nine Months: Other operating expenses decreased due to lower expenses for rent ($120) and investor relations ($15), partially offset by increases in computer software ($29), taxes ($24), and other operating expenses ($53), all for the nine months ended September 30, 2011 compared to the same period in 2010.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Depreciation and amortization	$ 520	$ 532	(2%)	$ 1,581	$ 2,283	(31%)

Three Months: Depreciation and amortization expense decreased to $520 for the three months ended September 30, 2011 from $532 for the three months ended September 30, 2010, primarily due to lower leasehold improvement amortization expenses.

Nine Months: Depreciation and amortization expense decreased to $1,581 for the nine months ended September 30, 2011 from $2,283 for the nine months ended September 30, 2010, primarily due to lower leasehold improvement amortization expenses.

Other income:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Percent Change	2011	2010	Percent Change
Interest income	$ 15	$ 17	(12%)	$ 49	$ 48	2%

Three Months: Interest income decreased to $15 for the three months ended September 30, 2011 from $17 for the three months ended September 30, 2011. For the three months ended September 30, 2011 and 2010, investment income decreased to $15 from $17, respectively, due to lower interest rates on cash equivalents in 2011 than in 2010.

Nine Months: Interest income increased to $49 for the nine months ended September 30, 2011 from $48 for the nine months ended September 30, 2010. For the nine months ended September 30, 2011 and 2010, investment income remained unchanged at $49, while the amortization of premiums, net of discounts, was $0 and ($1) for the nine months ended September 30, 2011 and 2010, respectively.

Interest income, as reported, is primarily the result of investment income from our auction rate securities and money market funds, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those securities.

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Income Taxes:

For the three months ended September 30, 2011, GAAP loss was $11,432 and for the nine months ended September 30, 2011, GAAP income was $21,127. As a result of the $60.0 million Salix upfront cash payment, $0.2 million payment in respect of Salix ex-U.S. sublicensee revenue and $13.9 million in reimbursements received under the Salix License Agreement, we have income for tax purposes, which we expect to offset fully with net operating loss carry-forwards. For the three and nine months ended September 30, 2010, we had losses both for GAAP and tax purposes.

Liquidity and Capital Resources

We have to date relied principally on external funding, collaborations with Salix, Wyeth and others, royalty and product revenue to finance our operations. We have funded operations through private placements of equity securities, public offerings of common stock, payments received under collaboration agreements, funding under government research grants and contracts, interest on investments, proceeds from the exercise of options and warrants, and through September 30, 2011, sales of our common stock under our two employee stock purchase plans (Purchase Plans). Under the February 2011 Salix License Agreement, we received through September 30, 2011, $60.2 million upfront cash payments and are eligible to receive development and commercialization milestone payments plus royalties on net sales and 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Salix receives from ex-U.S. sublicensees.

Our expenses and reimbursement revenue related to RELISTOR have declined substantially in the second half of 2011, since Salix assumed direct responsibility for expenses under third-party contracts we have assigned to it, and we are continuing to perform limited development tasks. Under the Salix License Agreement, we are reimbursed for Salix approved full-time equivalents (FTE) and third-party development expenses incurred and paid by us after February 3, 2011. For the three and nine months ended September 30, 2011, we incurred approximately $3.5 million and $22.2 million, respectively, of RELISTOR related expenses for which we have received reimbursements totaling $13.9 million through September 30, 2011, and in respect of which we expect to receive $0.7 million during the fourth quarter. We will not be reimbursed by Salix or Wyeth for $6.5 million of 2011 RELISTOR expenses incurred prior to the February Salix license agreement or expenses otherwise not reimbursable under the license or the Wyeth Transition Agreement.

In connection with the reorientation of our research and development focus on oncology, we are allocating additional financial and personnel resources to our PSMA ADC program, where we are conducting a phase 1 clinical trial of a proprietary, fully human monoclonal ADC directed against PSMA for the treatment of prostate cancer, and our pre-clinical development work on novel multiplex PI3K inhibitors for the treatment of cancer, and are seeking to in-license or acquire complementary opportunities in the oncology field. The Company is looking to out-license programs not within its oncology focus. While we have to date conducted PSMA ADC research and development on our own, we are considering as appropriate strategic collaborations with biopharmaceutical companies for PSMA ADC.

At September 30, 2011, we held $78.0 million in cash and cash equivalents, a $4.4 million decrease from $82.4 million at June 30, 2011, and a $30.1 million increase from $47.9 million at December 31, 2010. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. In addition, at September 30, 2011, our investment in auction rate securities classified as long-term assets on the Consolidated Balance Sheets amounted to $3.4 million.

We may require additional funding in the future, and if we are unable to enter into favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some

current operations, and/or reduce salary and other overhead expenses, to extend our remaining operations.

Our cash flow from operating activities was positive for the nine months ended September 30, 2011, due to the receipt in 2011 of $60.2 million Salix upfront payments and $14.7 million in reimbursement payments from Salix and Wyeth, partially offset by expenditures on our research and development programs and general and administrative costs. Our cash flow from operating activities was negative for the nine months ended September 30, 2010, due primarily to the excess of expenditures on our research and development programs and general and administrative costs over cash received from collaborators and government grants to fund such programs, as described below.

During the third quarter, we put in place a shelf registration statement with the SEC covering potential issuance(s) of up to $100.0 million of common stock, preferred stock, debt securities, warrants, other rights and units. We do not have any current plans for using this facility, which is available for issuances up to three years from the registration statement’s effective date.

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Sources of Cash

Operating Activities. During the nine months ended September 30, 2011, we received $77.9 million under our collaborations, consisting of (i) $60.0 million Salix upfront, (ii) $0.2 million in respect of Salix ex-U.S. sublicensee revenue and (iii) $13.9 million in reimbursement payments under the Salix License Agreement, (iv) $3.3 million under the Transition Agreement with Wyeth, and (v) $0.5 million in royalties. During the nine months ended September 30, 2010, we received $7.9 million under our collaborations, consisting of $6.1 million under the Transition Agreement with Wyeth and $1.8 million in royalties.

Under the Transition Agreement, Wyeth paid us $10.0 million in six quarterly installments through January 2011, and continued to pay royalties on 2010 ex-U.S. net sales as provided in the 2005 collaboration agreement that were due to us prior to September 30, 2010. Royalties or other revenues from RELISTOR after this transition period will be dependent on Salix's and its sublicensees' commercialization efforts. Wyeth is also providing financial resources to us and Salix of approximately $9.5 million, of which we have recognized $1.6 million for the nine months ended September 30, 2011 and $1.2 million in 2010, for development of a multi-dose pen for subcutaneous RELISTOR and $6.7 million remains available to support development activities assumed by Salix.

Under our License Agreement with Ono, we are entitled to receive potential milestone payments, upon achievement of development milestones by Ono, of up to $20.0 million, commercial milestones and royalties on sales of subcutaneous RELISTOR in Japan. Ono is also responsible for development and commercialization costs for subcutaneous RELISTOR in Japan.

We have partially funded research programs through awards from the NIH. For the nine months ended September 30, 2011 and 2010, we received $4.3 million and $2.4 million, respectively, of revenue from all NIH awards. We expect funding from the NIH to decline in the future to the extent we out-license existing NIH-funded programs not in the oncology area.

Changes in Accounts receivable and Accounts payable for the nine months ended June 30, 2011 and 2010 resulted from the timing of receipts from the NIH, Salix, Wyeth and Ono, and payments made to trade vendors in the normal course of business.

Other than amounts to be received from Salix, Wyeth, and Ono, 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. Our investments in auction rate securities during the first nine months of 2011 and auction rate securities and corporate debt securities during the first nine months of 2010 period covered by this report, are classified as available-for-sale. A substantial portion of our cash and cash equivalents at September 30, 2011, ($78.0 million) which include money market funds ($71.0 million) are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee program. Our auction rate securities ($3.4 million) include $2.5 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.

Financing Activities. During the nine months ended September 30, 2011 and 2010, we received cash of $3.2 million and $3.0 million, respectively, from the exercise of stock options 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.

Unless we obtain regulatory approval from the FDA for additional product candidates and/or enter into agreements with corporate collaborators with respect to our additional technologies, we will be required to fund our operations in the future through sales of common stock or other securities, royalty or other financing agreements and/or grants and government contracts. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us may seriously jeopardize the future success of our business.

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Uses of Cash

Operating Activities. The majority of our cash has been used to advance our research and development programs. Our total expenses for research and development from inception through September 30, 2011 have been approximately $627.5 million. For various reasons, including the early stage of certain of our programs, the timing and results of our clinical trials, our dependence in certain instances on third parties, 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, 2011 and 2010, research and development costs, which do not reflect research and development amounts due to us under our collaborations, incurred by project were as follows:

	Nine Months Ended September 30,	
	2011	2010
	(in millions)	
RELISTOR	$ 22.2	$ 13.7
Cancer	12.7	11.7
HIV	3.5	4.6
Other	7.3	6.9
Total	$ 45.7	$ 36.9

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

Investing Activities. During the nine months ended September 30, 2011 and 2010, we spent $0.1 million and $2.1 million, respectively, on capital expenditures.

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, 2011 for future payments under these agreements:

		Payments due by September 30,			
	Total	2012	2013-2014	2015-2016	Thereafter
			(in millions)		
Operating leases	$ 38.4	$ 3.3	$ 7.4	$ 8.4	$ 19.3
License and collaboration agreements:					
- Fixed payments	2.4	0.2	0.5	0.6	1.1
- Contingent payments (1)	84.0	1.0	3.3	-	79.7
Total	$ 124.8	$ 4.5	$ 11.2	$ 9.0	$ 100.1

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

We periodically assess the scientific progress and merits of each of our programs to determine if continued research and development is commercially and economically viable. Certain of our programs have been terminated due to the lack of scientific progress and prospects for ultimate commercialization. Because of the uncertainties associated with research and development 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.

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Off-Balance Sheet Arrangements and Guarantees

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

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America. Our significant accounting policies are disclosed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010. 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.

In October 2009, the FASB updated ASC 605 Revenue Recognition by specifying how to separate deliverables in multiple-deliverable arrangements, and how to measure and allocate arrangement consideration to one or more units of accounting. Under ASC 605, the delivered item(s) are separate units of accounting, provided (i) the delivered item(s) have value to a collaborator on a stand-alone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We adopted this update on January 1, 2011. In April 2010, the FASB issued a separate update to ASC 605 which provides guidance on the criteria that should be met when determining whether the milestone method of revenue recognition is appropriate. This method is effective on a prospective basis for milestones achieved after January 1, 2011. We did not achieve any milestones between that date and September 30, 2011; after a milestone is achieved, we will determine whether or not to make a policy election to adopt the milestone method.

There have been no other changes to our critical accounting policies and estimates as of and for the nine months ended September 30, 2011, which are disclosed in Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our 2010 Annual Report on Form 10-K.

Recently Issued Accounting Standards

In June 2011, the FASB issued ASU No. 2011-05, which requires that comprehensive income and the related components be presented in a single continuous statement or in two separate but consecutive statements. The ASU, which is applied retrospectively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We are currently evaluating the effect this ASU will have on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is the result of joint efforts by the FASB and International Accounting Standards Board to develop a single, converged fair value framework. The converged guidance specifies how to measure fair value and what disclosures to provide about fair value measurements. The ASU is effective for interim and annual periods beginning after December 15, 2011. We are currently evaluating the effect this ASU will have on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary investment objective is to preserve principal. Our available-for-sale investments consist of money market funds and auction rate securities, all of which had interest rates that were variable and totaled $74.4 million at September 30, 2011. As a result, we do not believe that we have a material exposure to interest-rate risk.

At September 30, 2011, we continue to hold approximately $3.4 million (4.6% of assets measured at fair value) of auction rate securities, in respect of which we have received all scheduled interest payments. The principal amount of these remaining auction rate securities will not be accessible until the issuer calls or restructures the underlying security, the underlying security matures and is paid or a buyer outside the auction process emerges.

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We 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. 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, 2011 and the temporary impairment amount of $276 at September 30, 2011 decreased from $292 at December 31, 2010. A 100 basis point increase to our internal analysis would result in an insignificant increase in the temporary impairment of these securities as of the nine months ended September 30, 2011.

Item 4. Controls and Procedures

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

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

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

PART II — OTHER INFORMATION

Item 1A. Risk Factors

Our business and operations entail a variety of serious risks and uncertainties, including those described in Item 1A of our Form 10-K for the year ended December 31, 2010 and our other public reports. In addition, the following risk factors have changed during the three month period ended September 30, 2011.

Overview; Significance of our new focus on oncology.

Our business and operations entail a variety of serious risks and uncertainties. Our business is inherently risky. We are subject to the risks of failure inherent in the development of product candidates based on new technologies. We, or in the case of RELISTOR, our collaborators, must complete successfully clinical trials and obtain regulatory approvals for our product candidates, all of which (other than RELISTOR) are in pre-clinical or early clinical development. We now rely on Salix to complete development and obtain regulatory approvals for additional formulations of and indications for RELISTOR, and in the Japanese market, we rely on Ono to conduct successful clinical trials and obtain regulatory approvals.

As we transition to an oncology-focused research and development strategy, these risks will continue to be significant. The overall riskiness of our business may increase to the extent the oncology space becomes more competitive or less favored in the commercial marketplace. Some of the components of our new focus particularly affect our manufacturing capabilities, clinical trial activities and grant-based resources, as discussed below. The research and development programs on which we have historically and are now focusing involve novel approaches to human therapeutics. There is little precedent for the successful commercialization of products based on our technologies, and there are a number of technological challenges that we must overcome to complete most of our development efforts. We may not be able successfully to develop further any of our products.

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In addition to the risks we face in our research and development activities, and our business as a publicly held commercial enterprise devoted to developing and commercializing high-technology consumer products, the transitioning of RELISTOR to our new partner Salix presents us with new risks. Those risks, as well as major risks we face in both our own research and development efforts and Salix's and Ono's development and commercialization efforts for RELISTOR, include the following:

We are dependent on Salix, Ono and other business partners to develop and commercialize RELISTOR in their respective areas, exposing us to significant risks.

We are and will be dependent upon Salix, Ono and any other business partner(s) with which we may collaborate in the future to perform and fund development, including clinical testing of RELISTOR, make related regulatory filings and manufacture and market products, including for new indications and in new formulations, in their respective territories. Revenues from the sale of RELISTOR now depend almost entirely upon the efforts of Salix and its sublicensees, which will have significant discretion in determining the efforts and resources it applies to sales of RELISTOR. Ono will have similar discretion with respect to sales in Japan. Neither may be effective in obtaining approvals for new indications and/or formulations or in marketing existing or future products. Our business relationships with Salix, Ono and other partners may not be scientifically, clinically or commercially successful. For example, Salix is a larger pharmaceutical company than Progenics with a variety of marketed products. Unlike Wyeth and Pfizer, however, Salix is not a large diversified pharmaceutical company and does not have resources commensurate with those companies. Salix has its own corporate objectives, which may not be consistent with our best interests, and may change its strategic focus or pursue alternative technologies in a manner that results in reduced or delayed revenues to us. Changes of this nature might also occur if Salix were acquired or if its management changed.

We may have future disagreements with Salix 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 extensive financial and operational consequences to us, and have a material adverse effect on our business, results of operations and financial condition.

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

Our business and 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. Under our License Agreement with Salix, we are dependent on it for compliance with these regulations as they apply to RELISTOR.

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

As described in our most recent Annual Report on Form 10-K under Business – Competition, we are aware of a number of products and product candidates which compete or may potentially compete with RELISTOR. Any of these approved products or product candidates, or others which may be developed in the future, may achieve a significant competitive advantage relative to RELISTOR, and, in any event, the existing or future marketing and sales capabilities of these competitors may impair Salix's and/or Ono's ability to compete effectively in the market.

We are also aware of competitors described in that section who are developing alternative treatments for disease targets to which our research and development programs are directed, any of which – or others which may be developed in the future – may achieve a significant competitive advantage relative to any product we may develop.

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Setbacks in clinical development programs could adversely affect us.

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

Ono is conducting required clinical trials with Japanese patients to obtain regulatory approval of RELISTOR in Japan. There can be no assurance that these clinical trials will yield results adequate for that regulatory approval.

If the results of current or future clinical studies of our product candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved. With the reorientation of our research and development focus on oncology, such events could have a material adverse effect on the Company.

Clinical trials often take longer than expected.

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, and with the reorientation of our research and development focus on oncology, such events could have a material adverse effect on the Company. Delays can be caused by, among other things:

- deaths or other adverse medical events involving subjects in our clinical trials;
- regulatory or patent issues;
- interim or final results of ongoing clinical trials;
- failure to enroll clinical sites as expected;
- competition for enrollment from clinical trials conducted by others in similar indications;
- scheduling conflicts with participating clinicians and clinical institutions;
- 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 License Agreement with Salix, Salix generally has responsibility for conducting RELISTOR clinical trials, including all trials outside of the United States other than Japan, where Ono has the responsibility for clinical trials. We have effectively no control over the timing and other aspects of these clinical trials.

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

Salix or Ono may not be able to fulfill manufacturing obligations for RELISTOR, either on their own or through third-party suppliers. Our existing arrangements with suppliers for 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. 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. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product. A delay or disruption of supplies of RELISTOR would have a material adverse effect on the RELISTOR franchise, and therefore on our business as a whole.

We have limited manufacturing capabilities, which could adversely affect our ability to commercialize products.

Under our License Agreement with Salix, Salix is responsible for obtaining supplies of RELISTOR, and has assumed relationships we entered into in anticipation of establishing a new collaboration partnership or contracted with other contract manufacturing organizations (CMOs) for supply of RELISTOR active pharmaceutical ingredient (API) and subcutaneous and oral finished drug product. These arrangements may not be on optimally-advantageous terms, and will subject us to risks that the counterparties may not perform optimally in terms of quality or reliability.

As part of the reorientation of our research and development focus on oncology, we are in the process of closing our current Good Manufacturing Practices (cGMP) manufacturing facility, and will therefore be more reliant on collaborators or other third parties to assist with production.

With respect to our other product candidates, our limited manufacturing capabilities may result in increased costs of production or delay product development or commercialization. In order to commercialize our product candidates successfully, we or our collaborators would need to be able to manufacture products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. Manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up for large-scale production and subject to delays, inefficiencies and low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available to us on a timely basis or at all, our clinical trials could be seriously delayed, since these materials are time consuming to manufacture and cannot be readily obtained from third-party sources.

If we were to decide to establish a commercial-scale manufacturing facility in the future, we would require substantial additional funds and be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive.

We have entered into arrangements with third parties for the manufacture of some of our product candidates and, in some cases, new means of administration for these product candidates. Our third-party sourcing strategy may not result in a cost-effective means for manufacturing products. In employing third-party manufacturers, we do not control many aspects of the manufacturing process, including compliance with cGMP and other regulatory requirements. We may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

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 has been to in-license technology and product candidates from academic and government institutions in order to minimize investments in early research. We originally gave Wyeth a license for development and commercialization of RELISTOR, and are now dependent primarily on Salix and Ono. We may not be able to maintain our relationships with Salix or Ono, or establish new ones for RELISTOR or other drug candidates 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.

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We lack sales and marketing infrastructure and related staff, which will require significant investment to establish and in the meantime may make us dependent on third parties for their expertise in this area.

We have no established sales, marketing or distribution infrastructure. If we receive marketing approval for a pharmaceutical product, significant investment, time and managerial resources will be required to build the commercial infrastructure required to market, sell and support it. Should we choose to commercialize a product directly, we may not be successful in developing an effective commercial infrastructure or in achieving sufficient market acceptance. Alternatively, we may choose to market and sell products through distribution, co-marketing, co-promotion or licensing arrangements with third parties. We may also consider contracting with a third party professional pharmaceutical detailing and sales organization to perform the marketing function for one or more products. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of product candidates, any revenues we receive will depend primarily on the efforts of third parties. We will not control the amount and timing of marketing resources these third parties devote to our products.

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

A portion of our revenues to date has been derived from federal government grants and research contracts. During the last three years, we generated revenues from awards made to us by the NIH to partially fund some of our programs. Most of these resources have been directed toward candidates which we are now seeking to out-license as part of the reorientation of our research and development focus on oncology. In any event, we cannot rely on grants or additional contracts as a continuing source of funds, as funds available under these grants and/or contracts must be applied toward the research and development programs specified by the government rather than for all our programs generally, and the government’s obligation to make payments under these grants and/or contracts is subject to appropriation by the U.S. Congress for funding in each year, which is subject to being scaled back due to budgetary constraints and the results of periodic audits.

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. We have put in place a shelf registration statement with the SEC covering potential issuance(s) of up to $100.0 million of common stock, preferred stock, debt securities, warrants, other rights and units. Sales of securities pursuant to this registration statement could cause the market price or our stock to decline. In addition, we have put in place registration statements covering issuances of shares pursuant to our equity compensation 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.

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Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	Statement re computation of ratio of earnings (loss) to combined fixed charges and preferred stock dividends.
31.1	Certification of Mark R. Baker, Chief Executive Officer of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Robert A. McKinney, Chief Financial Officer and Senior Vice President, Finance and Operations (Principal Financial and Accounting Officer) of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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SIGNATURES

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

PROGENICS PHARMACEUTICALS, INC.

Date: November 9, 2011 By: /s/ Robert A. McKinney
Robert A. McKinney, CPA
Chief Financial Officer
Senior Vice President, Finance & Operations
(Duly authorized officer of the Registrant and
Principal Financial and Accounting Officer)