

PROGENICS PHARMACEUTICALS INC  
Form 10-Q  
November 12, 2013

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

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 (I.R.S. Employer Identification Number)  
incorporation or organization)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of November 6, 2013, a total of 60,825,404 shares of common stock, par value \$.0013 per share, were outstanding.

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## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements

PROGENICS PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS

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

	September 30, 2013 (Unaudited)	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 75,597	\$ 58,838
Accounts receivable	754	6,937
Other current assets	1,221	1,692
Total current assets	77,572	67,467
Auction rate securities	2,208	3,240
Fixed assets, at cost, net of accumulated depreciation and amortization	2,526	3,399
Deferred tax asset – long term	-	2,052
Intangible assets (Note 3)	32,300	-
Goodwill	7,702	-
Other assets	150	150
Total assets	\$ 122,458	\$ 76,308
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,904	\$ 5,640
Deferred tax liability – current	-	2,069
Deferred revenue – current	53	838
Other current liabilities	115	115
Total current liabilities	6,072	8,662
Acquisition-related contingent consideration liability	15,900	-
Deferred tax liability – long term	12,683	-
Other liabilities	915	1,078
Total liabilities	35,570	9,740
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$.001 par value; 20,000,000 shares authorized; issued and outstanding - none	-	-
Common stock, \$.0013 par value; shares authorized - 160,000,000 in 2013 and 80,000,000 in 2012; issued - 61,025,404 in 2013 and 46,765,472 in 2012	79	61
Additional paid-in capital	547,868	493,613
Accumulated deficit	(458,126 )	(424,105 )
Accumulated other comprehensive loss	(192 )	(260 )
Treasury stock, at cost (200,000 shares in 2013 and 2012)	(2,741 )	(2,741 )
Total stockholders' equity	86,888	66,568
Total liabilities and stockholders' equity	\$ 122,458	\$ 76,308

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

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PROGENICS PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Royalty income	\$719	\$728	\$3,052	\$4,181
Collaboration revenue	145	136	1,512	521
Research grants	-	243	275	417
Other revenues	3	10	55	44
Total revenues	867	1,117	4,894	5,163
Expenses:				
Research and development	7,913	7,551	26,702	26,417
License fees – research and development	91	510	314	660
Royalty expense	73	73	308	420
General and administrative	3,123	4,007	10,853	11,753
Depreciation and amortization	179	291	774	1,063
Total expenses	11,379	12,432	38,951	40,313
Operating loss	(10,512)	(11,315)	(34,057)	(35,150)
Other income:				
Interest income	12	14	36	43
Total other income	12	14	36	43
Net loss	\$(10,500)	\$(11,301)	\$(34,021)	\$(35,107)
Net loss per share – basic and diluted	\$(0.17 )	\$(0.33 )	\$(0.63 )	\$(1.04 )
Weighted-average shares – basic and diluted	60,599	33,848	54,104	33,803

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

PROGENICS PHARMACEUTICALS, INC.  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(amounts in thousands)  
 (Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	\$(10,500)	\$(11,301)	\$(34,021)	\$(35,107)
Other comprehensive income:				
Net change in unrealized loss on auction rate securities	-	-	68	8
Total other comprehensive income	-	-	68	8
Comprehensive loss	\$(10,500)	\$(11,301)	\$(33,953)	\$(35,099)

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

PROGENICS PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

(amounts in thousands)  
(Unaudited)

	Common Stock			Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount	Additional Paid-In Capital			Shares	Amount	
Balance at December 31, 2012	46,765	\$ 61	\$493,613	\$(424,105 )	\$ (260 )	(200)	\$(2,741)	\$66,568
Net loss	-	-	-	(34,021 )	-	-	-	(34,021)
Other comprehensive income	-	-	-	-	68	-	-	68
Compensation expenses for share-based payment arrangements	-	-	2,903	-	-	-	-	2,903
Acquisition of subsidiary, net of issuance costs	4,472	6	11,214	-	-	-	-	11,220
Sale of common stock in public offering, net of underwriting discounts and commissions (\$2,581) and offering expenses (\$350)	9,775	12	40,067	-	-	-	-	40,079
Forfeitures of restricted stock	(1 )	-	-	-	-	-	-	-
Exercise of stock options	14	-	71	-	-	-	-	71
Balance at September 30, 2013	61,025	\$ 79	\$547,868	\$(458,126 )	\$ (192 )	(200)	\$(2,741)	\$86,888

	Common Stock			Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount	Additional Paid-In Capital			Shares	Amount	
Balance at December 31, 2011	34,046	\$ 44	\$463,440	\$(388,674 )	\$ (268 )	(200)	\$(2,741)	\$71,801
Net loss	-	-	-	(35,107 )	-	-	-	(35,107)
Other comprehensive income	-	-	-	-	8	-	-	8
Compensation expenses for share-based payment arrangements	-	-	5,750	-	-	-	-	5,750
Forfeitures of restricted stock	(6 )	-	-	-	-	-	-	-
Exercise of stock options	37	-	196	-	-	-	-	196
Balance at September 30, 2012	34,077	\$ 44	\$469,386	\$(423,781 )	\$ (260 )	(200)	\$(2,741)	\$42,648

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



PROGENICS PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)  
(Unaudited)

	For the Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	\$(34,021)	\$(35,107)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	774	1,063
Losses (gains) on sales of fixed assets	214	(307 )
Expenses for share-based compensation awards	2,903	5,750
Changes in assets and liabilities:		
Decrease in accounts receivable	6,240	387
Decrease (increase) in other current assets	1,041	(244 )
(Decrease) increase in accounts payable and accrued expenses	(2,565 )	155
(Decrease) in deferred revenue - current	(833 )	-
(Decrease) in deferred revenue – long term	-	(153 )
(Decrease) in other liabilities	(163 )	(458 )
Net cash used in operating activities	(26,410)	(28,914)
Cash flows from investing activities:		
Cash acquired in acquisition of subsidiary	1,888	-
Capital expenditures	(77 )	(759 )
Proceeds from sales of fixed assets	153	368
Proceeds from redemption of auction rate securities	1,100	100
Net cash provided by (used in) investing activities	3,064	(291 )
Cash flows from financing activities:		
Equity issuance costs in connection with acquisition of subsidiary	(45 )	-
Proceeds from public offering of common stock, net of underwriting discounts and commissions and offering expenses	40,079	-
Proceeds from the exercise of stock options	71	196
Net cash provided by financing activities	40,105	196
Net increase (decrease) in cash and cash equivalents	16,759	(29,009)
Cash and cash equivalents at beginning of period	58,838	70,105
Cash and cash equivalents at end of period	\$75,597	\$41,096
Supplemental disclosure of cash flow information:		
Acquisition-related contingent consideration liability	\$15,900	\$-
Stock acquisition consideration	\$11,265	\$-

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

PROGENICS PHARMACEUTICALS, INC.

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

1. Interim Financial Statements

Progenics Pharmaceuticals, Inc. develops innovative medicines for oncology. A significant part of our research and development efforts centers on prostate specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. We are conducting phase 2 clinical trials of two product candidates for prostate cancer targeted toward PSMA: our therapeutic candidate, PSMA ADC, a fully human monoclonal antibody-drug conjugate (ADC), and MIP-1404, an imaging agent candidate in development by our Molecular Insight Pharmaceuticals (MIP) subsidiary. Among other assets in our pipeline of targeted radiotherapy and molecular imaging compounds are a group of small molecule therapeutics, MIP-1095, -1555 and -1558, in preclinical study for metastatic prostate cancer and other PSMA-expressing cancers, and Azedra™, an ultra-orphan radiotherapy candidate in a pivotal phase 2 clinical trial for pheochromocytoma.

Progenics has developed internally and acquired from research institutions, pharmaceutical and biotechnology companies certain compounds and technologies which we are advancing with other parties, including our first commercial drug, Relistor® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation (OIC), which we have licensed to Salix Pharmaceuticals, Inc. worldwide other than Japan, where we have licensed the subcutaneous formulation of the drug to Ono Pharmaceutical Co., Ltd. We have suspended investment in our proprietary phosphoinositide 3-kinase (PI3K) inhibitor research and are evaluating alternative paths forward for this program. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving our proprietary research, development and clinical programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

Our current principal sources of revenue from operations are upfront, commercialization milestones, royalty and revenue-sharing payments from Salix's Relistor operations. Royalty and milestone payments from Relistor depend on success in development and commercialization, which is dependent on many factors, such as the actions of Salix and Ono, decisions by the FDA and other regulatory bodies, the outcome of clinical and other testing of Relistor, and, to the extent requested by our collaboration partners, our own efforts. We and Salix have sought to expand the availability of subcutaneous Relistor to patients taking opioids for non-cancer pain and who suffer from OIC as a result, and to develop an oral formulation of methylnaltrexone for use by such patients. Salix and Progenics have continued to work together with the FDA to generate a reasonable path forward for the further development and regulatory review of Relistor in light of the FDA's complete response action taken in July 2012 regarding Salix's Relistor sNDA for chronic pain, in which the FDA requested additional data. After an End-of-Review meeting in October 2012, the FDA's Division of Gastroenterology and Inborn Errors Products expressed a concern that there may be a risk associated with the chronic use of mu-opioid antagonists in patients who are taking opioids for chronic pain, and, in order to understand this potential risk, the Division communicated that a very large, well-controlled, chronic administration trial will have to be conducted to assess the safety of any mu-opioid antagonist prior to market approval for the treatment of patients with OIC who are taking opioids for chronic, non-cancer pain. Salix subsequently held discussions with the Division and expressed the view that the post-marketing, clinical and preclinical data currently available for Relistor adequately demonstrate an appropriate and expected safety profile sufficient to permit the approval of the current Relistor sNDA. In response to Salix's formal appeal of the FDA's complete response letter, the FDA has informed Salix and Progenics that it will seek input from an Advisory Committee, which is expected to convene on March 10-11, 2014. The FDA has also stated that it will take action under the appeal within 30 days after receiving input from the Committee.

Progenics in October commenced an arbitration with Ono under the provisions of the parties' License Agreement, following a communication from Ono that it has determined to discontinue development of subcutaneous Relistor in

Japan because of "commercial concerns" that Ono contends would permit it to cease development and terminate the Agreement. Under our Agreement with Ono, Ono may cease development of subcutaneous Relistor only if it terminates the License Agreement, which it may do unilaterally only if Progenics is in material default. Progenics is not in default under the Agreement, and Ono has neither asserted that Progenics is, nor terminated the Agreement.

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.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

Relistor is a first-in-class therapy for OIC which we developed over the course of the last decade and since 2008 has been approved for sale in the United States and over 50 other countries worldwide, including countries in the European Union, Canada and Australia. Under our Agreement with Salix, we are eligible to receive (i) a development milestone of up to \$40 million upon U.S. marketing approval for subcutaneous Relistor in non-cancer pain patients (the proposed indication addressed in the complete response action mentioned above), (ii) a development milestone of up to \$50 million upon U.S. marketing approval of an oral formulation of Relistor, (iii) up to \$200 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 either marketing approval is subject to a Black Box Warning or Risk Evaluation and Mitigation Strategy (REMS), payment of a substantial portion of the development milestone amount would be deferred, and subject, to achievement of the first commercialization milestone (payable on annual U.S. sales first exceeding \$100 million).

In the second quarter of this year, we completed an underwritten public offering of 8.5 million shares of common stock at a public offering price of \$4.40 per share, resulting in net proceeds of approximately \$34.8 million. Exercise of the underwriters' overallotment option on an additional 1.3 million shares in July 2013 resulted in additional net proceeds of approximately \$5.2 million in the current third quarter.

Funding and Financial Matters. At September 30, 2013, we held \$75.6 million in cash (\$5.242 million) and cash equivalents (money market funds of \$70.355 million), a \$3.6 million decrease from the second quarter-end, and a \$16.8 million increase from 2012 year-end. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We currently use cash on hand, royalty payments from Relistor and proceeds from two recent common stock offerings to fund our ongoing operations. We expect to continue to use cash on hand and future Relistor royalties and other revenues, including any future development and/or commercialization milestones, as well as payments we may receive for licenses or other transactions involving other proprietary assets and programs, to fund our operations in the future. If we do not realize sufficient royalty or other revenue from Relistor, or 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 certain programs, and/or take other economic measures.

## 2. Significant Accounting Policies

In addition to the policies described in Note 2 to the consolidated financial statements included in our 2012 Annual Report on Form 10-K, we apply the following significant accounting policies:

### Basis of Presentation

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 2012 Annual Report on Form 10-K. 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.

#### Use of Estimates

Significant estimates include useful lives of fixed assets, the periods over which certain revenues and expenses will be recognized, including collaboration revenue recognized from non-refundable up-front licensing payments and expense recognition of certain clinical trial costs which are included in research and development expenses, the amount of non-cash compensation costs related to share-based payments to employees and non-employees and the periods over which those costs are expensed, the likelihood of realization of deferred tax assets and the assumptions used in the valuations of in-process research and development, goodwill and contingent consideration liability.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

In-Process Research and Development

The fair values of in-process research and development (IPR&D) acquired in business combinations are capitalized. The Company utilizes the "income method," which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. IPR&D intangible assets which are determined to have a decline in their fair value are adjusted downward and an expense is recognized in the Consolidated Statements of Operations. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

Goodwill

Goodwill represents excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized, but is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. The Company determines whether goodwill may be impaired by comparing the carrying value of its reporting unit to the fair value of its reporting unit.

Fair Value Measurements

In accordance with ASC 820 Fair Value Measurements and Disclosures, we use a three-level hierarchy for fair value measurements of certain assets and liabilities for financial reporting purposes that distinguishes between market participant assumptions developed from market data obtained from outside sources (observable inputs) and our own assumptions about market participant assumptions developed from the best information available to us in the circumstances (unobservable inputs). We assign hierarchy levels to assets constituting our available-for-sale portfolio and to our contingent consideration liability arising from the MIP acquisition based on our assessment of the transparency and reliability of the inputs used in the valuation. ASC 820 defines the three hierarchy levels as:

- Level 1 - Valuations based on unadjusted quoted market prices in active markets for identical securities.
- Level 2 - Valuations based on observable inputs other than Level 1 prices, such as quoted prices for similar assets at the measurement date, quoted prices in markets that are not active or other inputs that are observable, either directly or indirectly.
- Level 3 - Valuations based on unobservable inputs that are significant to the overall fair value measurement, which as noted above involve management judgment.

Recurring Fair Value Measurements

We believe the carrying amounts of the Company's cash equivalents approximated their fair values as of September 30, 2013 and December 31, 2012 due to their short-term nature; we consider them Level 1 instruments. We also believe that the carrying values of accounts receivable, other current assets, other assets (restricted cash providing collateral for a letter of credit securing lease obligations) and accounts payable and accrued expenses approximate their fair values at those dates due to their short-term nature.

We believe the carrying amount of the contingent consideration liability arising from the MIP acquisition (see Note 3), which, as displayed in Note 6, we categorize as a Level 3 instrument, approximated its fair value (estimated as described in Note 3) as of September 30, 2013. The Company reviews the fair value of contingent consideration quarterly or whenever events or changes in circumstances occur that indicate there has been a change in the fair value.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

Nonrecurring Fair Value Measurements

The Company's non-financial assets, such as intangible assets and property and equipment, are measured and recorded at fair value on the acquisition date, and if indicators of impairment exist, we assess recoverability by measuring the amount of any impairment by comparing the carrying value of the asset to its then-current estimated fair value (for intangible assets) or to market prices for similar assets (for property and equipment). If the carrying value is not recoverable we record an impairment charge. In connection with the second quarter amendment of the Company's Tarrytown lease, we recognized impairment losses of \$347 on leasehold improvements and machinery and equipment removed from service which are included in Research and development expenses in our accompanying Consolidated Statements of Operation for the nine months ended September 30, 2013.

3. Acquisition of Molecular Insight Pharmaceuticals, Inc.

Molecular Insight's operations from January 18, 2013, the date we acquired this subsidiary, are included in the interim Consolidated Financial Statements. The acquisition consideration included 4,566,210 shares (500,000 of which were placed in escrow) of Progenics common stock in a private transaction not taxable to Progenics. Under the acquisition agreement, Progenics also agreed to pay to the stockholders potential milestones, in cash or Progenics stock at Progenics' option, of up to \$23 million contingent upon achieving specified commercialization events and up to \$70 million contingent upon achieving specified sales targets relating to all MIP products. 93,847 of the escrow shares have been returned to Progenics to date pursuant to financial adjustment provisions of the agreement.

The acquisition was accounted for using the acquisition method of accounting, under which assets and liabilities of the acquired entity are recorded at their respective fair values as of the acquisition date (estimated as described below) and added to those of the acquiring entity. The difference between the estimated fair value of the acquisition consideration and fair value of the identifiable net assets represents potential future economic benefits arising from combining Progenics and MIP, taking into account a deferred tax liability related to in process research and development (IPR&D) intangible assets, and has been recorded as goodwill. The results of operations of MIP's business, the estimated fair market values of the assets acquired and liabilities assumed, and goodwill are included in our consolidated financial statements since the date of the acquisition.

During the nine months ended September 30, 2013, the Company incurred \$790 in transaction costs related to the acquisition, which primarily consisted of legal, accounting and valuation-related expenses and reduced additional paid-in capital in the first quarter of 2013 by \$45 for acquisition-related equity issuance costs. No transaction costs were incurred during the current three month period. The transaction costs were recorded in general and administrative expenses in the accompanying consolidated statements of operations. During the three and nine months ended September 30, 2013, MIP's business contributed \$82 and \$828 of revenues and \$2,238 and \$8,597 of net loss, respectively.

**Preliminary Purchase Price Allocation:** We have accounted for the Molecular Insight acquisition by preliminarily allocating our estimate of the fair market value of the consideration we paid to the fair values of the assets acquired and liabilities assumed at the effective date of the acquisition, estimated using the valuation models summarized below. Given the uniqueness of and uncertainties attendant to the assets and liabilities, the derived values do not reflect actual transactions or quoted prices. This preliminary allocation may change if, as and when additional information, primarily pertaining to the acquired current assets and assumed current liabilities, becomes available. Under applicable accounting requirements, we must make the final determination of estimated fair values within one year of the acquisition date. Acquired intangible assets, including goodwill, are not deductible for tax purposes.





## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

	Amount
Consideration:	
Progenics common stock consideration	\$11,265
Contingent consideration (pursuant to future milestone obligations)	15,900
Total consideration	27,165
 Tangible assets acquired and liabilities assumed:	
Cash and cash equivalents	1,888
Accounts receivable	56
Other current assets	529
Fixed assets	249
Accounts payable, accrued expenses and deferred revenue - current	(2,876 )
Deferred tax liability – long term	(12,683)
Total tangible assets acquired and liabilities assumed	(12,837)
 Intangible assets - in process research and development	32,300
Total tangible and intangible assets acquired and liabilities assumed	19,463
 Goodwill	\$7,702

Intangible assets and goodwill: In connection with the acquisition of Molecular Insight, in process research and development and goodwill are initially measured at estimated fair value and capitalized as an intangible asset. We perform an impairment test for these intangibles annually in the fourth quarter, unless impairment indicators require an earlier evaluation. Upon and subject to commercialization of the Company's product candidates, the IPR&D will be amortized over its estimated useful life.

We valued as intangible assets the in process research and development projects acquired as follows:

- (i) MIP 1404, an imaging agent in phase 2 development, at an estimated fair value of \$23.2 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2017 and a 18% discount rate;
- (ii) Azedra, a drug candidate for the treatment of pheochromocytoma and paraganglioma in phase 2b development, and for neuroblastoma in phase 2a development, at an estimated fair value of \$4.9 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2017 and a 15% discount rate;
- (iii) small molecule therapeutic candidates MIP 1095, -1555 and -1558, in preclinical development for the treatment of prostate cancer, at an estimated fair value of \$2.7 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2021 and a 20% discount rate; and
- (iv) Onalta, a drug candidate in phase 2 development for the treatment of metastatic carcinoid and pancreatic neuroendocrine tumors, at an estimated fair value of \$1.5 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2014 and a 15% discount rate.

As presented in Note 6, we recorded a contingent consideration liability at an estimated fair value of \$15.9 million resulting from probability adjusted discounted cash flow and Monte Carlo simulation models which include estimates of significant milestone payments to former MIP stockholders under the acquisition agreement ranging from 2016 to 2022 and risk adjusted discount rates ranging from 10% to 12.5%.

Pro forma financial information (unaudited): The following unaudited pro forma information presents the results of operations of the combined companies for the periods indicated as if the acquisition had been consummated on January 1, 2012, combining the respective historical results of Progenics and MIP for each period. Non-recurring transaction expenses of \$790, incurred in the nine months ended September 30, 2013, are reflected in the pro forma information as if these were incurred in the corresponding 2012 period, due to the pro forma assumption of January 1, 2012 as the date of the acquisition consummation.

## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

	Three Months		Nine Months Ended	
	Ended		September 30,	
	September 30,	September 30,	September 30,	September 30,
	2013	2012	2013	2012
Revenues	\$867	\$1,286	\$4,899	\$5,434
Net loss	(10,500)	(16,408)	(35,185)	(54,419)
Basic and diluted loss per share	(0.17 )	(0.43 )	(0.65 )	(1.42 )

## 4. Revenue Recognition

The Company recognizes revenue from all sources based on the provisions of the SEC's Staff Accounting Bulletin (SAB) No. 104 (SAB 104) and ASC 605 Revenue Recognition. Under ASC 605, delivered items are separate units of accounting, provided (i) the delivered items 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 items is considered probable and substantially in our control. A separate update to ASC 605 provides guidance on the criteria that should be met when determining whether the milestone method of revenue recognition is appropriate.

There have been no changes as of and for the nine months ended September 30, 2013 to our revenue recognition accounting policies disclosed in Note 2 to the consolidated financial statements included in our 2012 Annual Report on Form 10-K.

Under our 2012 agreement with CytoDyn Inc. for our PRO 140 program, and a MIP out-license of rights to its Onalta™ product candidate, we received a total of \$3.7 million (\$3.5 million in October 2012 and \$0.2 million in March 2013) in upfront payments and are eligible for future milestone and royalty payments. In consideration for the upfront payments, we are responsible for delivering relevant know-how (including patent rights), inventory and non-reimbursable services. In respect of these deliverables, which have a stand-alone value and represent separate units of accounting, we recognized \$2,827 of revenue in 2012 and \$862 in 2013.

Under our Relistor license agreement with Salix, we have recognized \$123 and \$153 during the first nine months of 2013 and 2012, respectively, from the \$60.0 million upfront payment. We expect to recognize the remaining \$39 deferred revenue – current as we complete joint committee services in the future.

## 5. Net Loss Per Share

Our basic net loss per share amounts are computed by dividing net loss by the weighted-average number of common shares outstanding during the period. At the end of the 2012 periods presented below, 33,627 shares of unvested restricted stock with non-forfeitable rights to dividends were outstanding; all such shares were vested at the end of September 30, 2013 period. The allocation of 2012 net losses to these participating securities pursuant to the two-class method is not material to both basic and diluted earnings per share. For each of the periods presented below, we reported a net loss and, therefore, potential dilutive common shares were not included in computing diluted net loss per share since it would have been anti-dilutive. The calculations of net loss per share, basic and diluted, are as follows:

Net Loss	Weighted	Per
(Numerator)	Average	Share

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		Common Shares (Denominator) (in thousands)	Amount
Three months ended September 30, 2013			
Basic and diluted	\$ (10,500 )	60,599	\$ (0.17 )
Nine months ended September 30, 2013			
Basic and diluted	\$ (34,021 )	54,104	\$ (0.63 )
Three months ended September 30, 2012			
Basic and diluted	\$ (11,301 )	33,848	\$ (0.33 )
Nine months ended September 30, 2012			
Basic and diluted	\$ (35,107 )	33,803	\$ (1.04 )

## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

For these periods, anti-dilutive common shares excluded from diluted per share amounts consist of the following:

	Three Months Ended September 30,			
	2013		2012	
	Weighted	Weighted	Weighted	Weighted
	Average	Average	Average	Average
	Number	Number	Number	Number
	(in	(in	(in	(in
	thousands)	thousands)	thousands)	thousands)
	Exercise	Exercise	Exercise	Exercise
	Price	Price	Price	Price
Options	6,068	\$ 11.14	6,035	\$ 12.22
Unvested restricted stock	-		33	
Total	6,068		6,068	

	Nine Months Ended September 30,			
	2013		2012	
	Weighted	Weighted	Weighted	Weighted
	Average	Average	Average	Average
	Number	Number	Number	Number
	(in	(in	(in	(in
	thousands)	thousands)	thousands)	thousands)
	Exercise	Exercise	Exercise	Exercise
	Price	Price	Price	Price
Options	6,047	\$ 11.69	6,019	\$ 12.31
Unvested restricted stock	-		68	
Total	6,047		6,087	

## 6. Fair Value Measurements

We record auction rate securities 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 accumulated other comprehensive loss (see Note 2. Summary of Significant Accounting Policies - Fair Value Measurements in the notes to consolidated financial statements included in our 2012 Annual Report on Form 10-K). We also record the contingent consideration liability resulting from the MIP acquisition, as referenced in Note 3, at fair value in accordance with ASC 820-10-50.

The following tables present our money market funds and auction rate securities assets and contingent consideration liability measured at fair value on a recurring basis as of the dates indicated, classified by valuation hierarchy:

Balance at	Fair Value Measurements at		
	Quoted	Significant	Significant
September	Prices	Other	Unobservable
30, 2013	in	Observable	Inputs
	Active	Inputs	(Level 3)
	Markets	(Level 2)	
	for		
	Identical		
	Assets		

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		(Level 1)		
Assets:				
Money market funds	\$ 70,355	\$70,355	\$ -	\$ -
Auction rate securities	2,208	-	-	2,208
Total Assets	\$ 72,563	\$70,355	\$ -	\$ 2,208
Liability:				
Contingent consideration	\$ 15,900	\$-	\$ -	\$ 15,900
Total Liability	\$ 15,900	\$-	\$ -	\$ 15,900

## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

		Fair Value Measurements at December 31, 2012		
		Quoted Prices in Active Markets for		
	Balance at December 31, 2012	Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 56,224	\$56,224	\$ -	\$ -
Auction rate securities	3,240	-	-	3,240
Total Assets	\$ 59,464	\$56,224	\$ -	\$ 3,240

At September 30, 2013 we held \$2,208 in auction rate securities which are classified as Level 3. The fair value of these securities includes \$2,208 of U.S. government subsidized securities collateralized by student loan obligations, with maturities greater than 10 years. 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, 2013, 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.

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 or issuer calls of the securities, (ii) collateralization of underlying assets of the security and (iii) credit quality of the security. Significant increases (decreases) in the redemption period or discount rates would result in a significantly lower (higher) fair value measurement. In re-evaluating the valuation of these securities as of September 30, 2013, the temporary impairment amount, the duration of which is greater than 12 months, decreased from \$260 at December 31, 2012, to \$192, which is reflected as part of accumulated other comprehensive loss on our accompanying Consolidated Balance Sheets and based on such re-evaluation, we believe that we have the ability to hold these securities until recovery of fair value. 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.

The estimated fair value of the contingent consideration liability of \$15.9 million represents future potential milestone payments to former MIP stockholders. The Company considers this liability a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value was determined based on probability adjusted discounted cash flow and Monte Carlo simulation models that included significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs were the probabilities of achieving regulatory approval of the development projects and subsequent commercial success, and



discount rates. Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively. The Company reviews the fair value of the contingent consideration liability quarterly or whenever events or circumstances occur that indicate there has been a change in fair value; changes in estimated fair values are recorded in the general and administrative expenses in the Consolidated Statements of Operations.

## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

The following table presents quantitative information pertaining to the fair value measurement of the Level 3 inputs:

	Fair Value as of September 30, 2013	Valuation Technique	Unobservable Input	Range (Weighted Average)
Asset:				
Auction Rate Securities	\$ 2,208	Discounted cash flow model	Redemption period Discount rate	5 to 15 years (6 years) 0.375% - 2.031% (1.23%)
Contingent consideration liability:				
Azedra commercialization	\$ 2,300	Probability adjusted discounted cash flow model	Probability of success Period of milestone expected achievement Discount rate	40% 2016 10%
MIP – 1404 commercialization	\$ 2,000	Probability adjusted discounted cash flow model	Probability of success Period of milestone expected achievement Discount rate	31% 2017 10%
Small molecule therapeutics (MIP 1095, -1555, -1558) commercialization	\$ 500	Probability adjusted discounted cash flow model	Probability of success Period of milestone expected achievement Discount rate	19% 2020 10%
Net sales targets	\$ 11,100	Monte-Carlo simulation	Probability of success Period of milestone expected achievement Discount rate	19% - 40% (32.9%) 2018 - 2022 12.5%
	Fair Value as of December 31, 2012	Valuation Technique	Unobservable Input	Range (Weighted Average)
Asset:				
Auction Rate Securities	\$ 3,240	Discounted cash flow model	Redemption period	

	4 to 15 years (5.9 years) 0.125% - 2.102%
Discount rate	(0.71%)

## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

For those financial instruments with significant Level 3 inputs (all of which are auction rate securities), the following table summarizes the activities for the periods indicated:

	Asset – Auction Rate Securities Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended September 30, 2013 2012	
Balance at beginning of period	\$2,208	\$3,240
Transfers into Level 3	-	-
Transfers out of Level 3	-	-
Total gains (losses) Included in net loss	-	-
Included in other comprehensive loss	-	-
Settlements at par	-	-
Balance at end of period	\$2,208	\$3,240
Changes in unrealized gains or losses for the period included in earnings (or changes in net assets) for assets held at the end of the reporting period	\$-	\$-
	Asset – Auction Rate Securities Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Nine Months Ended September 30, 2013 2012	
Balance at beginning of period	\$3,240	\$3,332
Transfers into Level 3	-	-
Transfers out of Level 3	-	-
Total gains (losses) Included in net loss	-	-

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Included in other comprehensive loss	68	8
Settlements at par	(1,100)	(100 )
Balance at end of period	\$2,208	\$3,240
Changes in unrealized gains or losses for the period included in earnings (or changes in net assets) for assets held at the end of the reporting period	\$-	\$-

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## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

	Liability – Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended September 30, 2013      2012	
Balance at beginning of period	\$ 15,900	\$ -
Fair value of contingent consideration – acquisition of Molecular Insight	-	-
Fair value adjustment to contingent consideration included in net loss	-	-
Balance at end of period	\$ 15,900	\$ -
Changes in unrealized gains or losses for the period included in earnings (or changes in net assets) for liabilities held at the end of the reporting period	\$ -	\$ -

	Liability – Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Nine Months Ended September 30, 2013      2012	
Balance at beginning of period	\$ -	\$ -
Fair value of contingent consideration – acquisition of Molecular Insight	15,900	-
Fair value adjustment to contingent consideration included in net loss	-	-
Balance at end of period	\$ 15,900	\$ -
Changes in unrealized gains or losses for the period included in earnings (or changes in net assets) for liabilities held at the end of the reporting period	\$ -	\$ -

## 7. Accounts Receivable

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Our accounts receivable represent amounts due the Company from collaborators, royalty payments, research grants and the sales of research reagents. These amounts are considered to be short-term as they are expected to be collected within one year and we believe carrying value approximates fair value. Accounts receivable as of the dates indicated below consisted of the following:

	September 30, 2013	December 31, 2012
Collaborators	\$ 22	\$ 6,125
Royalties	730	781
Research grants	-	12
Other	2	19
Total	\$ 754	\$ 6,937

The decrease in accounts receivable as of September 30, 2013, is primarily due to collection in the first quarter of the \$5.0 million upfront payment related to the out-licensed C. difficile program.

## PROGENICS PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

## 8. Accounts Payable and Accrued Expenses

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

	September 30, 2013	December 31, 2012
Accrued consulting and clinical trial costs	\$ 2,565	\$ 2,193
Accrued payroll and related costs	2,110	1,552
Restructuring accrual	89	813
Legal and professional fees	833	774
Accounts payable	234	229
Other	73	79
Total	\$ 5,904	\$ 5,640

## 9. Restructuring

We reduced headcount in the third quarter of 2012, resulting in a restructuring accrual of \$1.9 million which was paid through August 2013. We also reduced headcount at MIP and Progenics in the first quarter of 2013, resulting in an approximately \$1.5 million restructuring charge which is being paid through the end of 2013. During the second quarter of 2013, we incurred other exit and contract termination costs, including those related to termination of the lease for MIP's Cambridge, Massachusetts facility (\$900) and amendment of the Company's Tarrytown, New York lease and consolidation within reduced facility space (\$459).

Activity in the 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.

	Severance and Related Benefits	Other Exit Costs	Contract Termination Costs	Total Restructuring Accrual
Balance at December 31, 2012	\$ 813	\$ -	\$ -	\$ 813
Additions, net	1,477	-	-	1,477
Payments	(854 )	-	-	(854 )
Balance at March 31, 2013	1,436	-	-	1,436
Additions, net	15	15	1,359	1,389
Payments	(914 )	(15 )	(1,359 )	(2,288 )
Balance at June 30, 2013	537	-	-	537
Additions, net	-	-	-	-
Payments	(448 )	-	-	(448 )
Balance at September 30, 2013	\$ 89	\$ -	\$ -	\$ 89

## 10. 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 usual and customary indemnification provisions. We generally reciprocally agree to indemnify, hold harmless and reimburse indemnified parties for losses suffered or incurred with respect to products or product candidates, use of such products or other actions taken or omitted by the parties. The maximum potential amount of future payments we could be required to make under these indemnification provisions is generally 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, 2013.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)

(dollar amounts in thousands, except per share amounts or as otherwise noted)

Progenics is a party to a proceeding brought by a former employee complaining that the Company violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating the former employee. The Company believes the former employee's claims are without merit and is contesting the matter vigorously. The federal District Court hearing the case issued in July an order denying our motion for summary judgment dismissing the former employee's complaint, making it likely that the proceeding will continue to trial. Given the inherent uncertainty attendant to the proceeding, it is not possible at this time to estimate the likelihood or potential magnitude of any outcome, and we have accordingly not recorded any associated liability in these interim 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 and other dispute resolution, environmental and other risks; the risk that we may not be able to enter into favorable collaboration or other relationships or that existing or future relationships may not proceed as planned; the risk that current and pending patent protection for our products may be invalid, unenforceable or challenged, or fail to provide adequate market exclusivity, or that our rights to in-licensed intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.

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

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

### Overview

General. Progenics Pharmaceuticals develops innovative medicines for oncology. A significant part of our research and development efforts centers on prostate specific membrane antigen (PSMA), where we are conducting phase 2

clinical trials of two product candidates for prostate cancer: our therapeutic candidate, PSMA ADC, and MIP-1404, an imaging agent candidate in development by our Molecular Insight Pharmaceuticals subsidiary. Among other assets in our pipeline of targeted radiotherapy and molecular imaging compounds are a group of small molecule therapeutics, MIP-1095, -1555 and -1558, in preclinical study for metastatic prostate cancer and other PSMA-expressing cancers, and Azedra™, an ultra-orphan radiotherapy candidate in phase 2 clinical trials, for pheochromocytoma and potential additional indications.

Our acquisition of the privately-held Molecular Insight included the issuance of Progenics common stock in a private transaction not taxable to Progenics, and its agreement to pay potential milestones, in cash or Progenics stock at its option, of up to \$23 million contingent upon achieving specified commercialization events and up to \$70 million contingent upon achieving specified sales targets relating to all MIP products. As described in Note 3 to the Consolidated Financial Statements, the acquisition was accounted for using the acquisition method of accounting, under which assets and liabilities of MIP were recorded at their estimated respective fair values as of the acquisition date and added to those of Progenics. The difference between the estimated fair value of the acquisition consideration and fair value of the identifiable net assets represents potential future economic benefits arising from combining Progenics and MIP, and has been recorded as goodwill. The results of operations of MIP's business from January 18, 2013, the closing date of the acquisition, the estimated fair market values of the assets acquired and liabilities assumed, and goodwill are included in our consolidated financial statements since the date of the acquisition and are included in the discussion and analysis below.

Progenics has developed internally and acquired from research institutions, pharmaceutical and biotechnology companies certain compounds and technologies which we are advancing with other parties, including our first commercial drug, Relistor<sup>®</sup> (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation (OIC), which we have licensed to Salix Pharmaceuticals, Inc. worldwide other than Japan, where we have licensed the subcutaneous formulation of the drug to Ono Pharmaceutical Co., Ltd. We have suspended investment in our proprietary phosphoinositide 3-kinase (PI3K) inhibitor research and are evaluating alternative paths forward for this program. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving our proprietary research, development and clinical programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

Our current principal sources of revenue from operations are upfront, commercialization milestone, royalty and revenue-sharing payments from Salix's Relistor operations. Royalty and milestone payments from Relistor depend on success in development and commercialization, which is dependent on many factors, such as the actions of Salix and Ono, decisions by the FDA and other regulatory bodies, the outcome of clinical and other testing of Relistor, and, to the extent requested by our collaboration partners, our own efforts. We and Salix have sought to expand the availability of subcutaneous Relistor to patients taking opioids for non-cancer pain and who suffer from OIC as a result, and to develop an oral formulation of methylnaltrexone for use by such patients. Salix and Progenics have continued to work together with the FDA to generate a reasonable path forward for the further development and regulatory review of Relistor in light of the FDA's complete response action taken in July 2012 regarding Salix's Relistor sNDA for chronic pain in which the FDA requested additional data. After an End-of-Review meeting in October 2012, the FDA's Division of Gastroenterology and Inborn Errors Products subsequently expressed a concern that there may be a risk associated with the chronic use of mu-opioid antagonists in patients who are taking opioids for chronic pain, and, in order to understand this potential risk, the Division communicated that a very large, well-controlled, chronic administration trial will have to be conducted to assess the safety of any mu-opioid antagonist prior to market approval for the treatment of patients with OIC who are taking opioids for chronic, non-cancer pain. Salix subsequently held discussions with the Division and expressed the view that the post-marketing, clinical and preclinical data currently available for Relistor adequately demonstrate an appropriate and expected safety profile sufficient to permit the approval of the current Relistor sNDA. In response to Salix's formal appeal of the FDA's complete response letter, the FDA has informed Salix and Progenics that it will seek input from an Advisory Committee, which is expected to convene on March 10-11, 2014. The FDA has also stated that it will take action under the appeal within 30 days after receiving input from the Committee.

Progenics in October commenced an arbitration with Ono under the provisions of the parties' License Agreement, following a communication from Ono that it has determined to discontinue development of subcutaneous Relistor in Japan because of "commercial concerns" that Ono contends would permit it to cease development and terminate the Agreement. Under our Agreement with Ono, Ono may cease development of subcutaneous Relistor only if it terminates the License Agreement, which it may do unilaterally only if Progenics is in material default. Progenics is not in default under the Agreement, and Ono has neither asserted that Progenics is, nor terminated the Agreement.

See Part II, Item 1A, Risk Factors.

Most of our expenditures are for research and development activities. During the nine months ended September 30, 2013, expenses for Oncology, primarily related to PSMA ADC and MIP-1404, were \$26.1 million compared to \$23.5 million in 2012. Expenses for Relistor and Other programs were \$0.5 million and \$0.7 million, respectively, during the nine months ended September 30, 2013 compared to \$1.4 million and \$2.6 million, respectively, for the same period in 2012. We expect to incur significant development expenses for our PSMA ADC and MIP-1404 products candidate as clinical trials progress, while expenses, and the resulting reimbursement revenue, related to Relistor depend on the amount of research and development work we perform upon request by Salix or Ono.

At September 30, 2013, we held \$75,597 in cash and cash equivalents, a decrease of \$3,624 from second quarter-end, and a \$16,759 increase from 2012 year-end. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We expect to incur operating losses during the near term. At September 30, 2013, cash, cash equivalents and auction rate securities increased \$15,727 to \$77,805 from \$62,078 at December 31, 2012.

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If we do not realize sufficient royalty or other revenue from Relistor, or 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 certain programs, and/or take other economic measures.

Relistor has been approved by regulatory authorities in the U.S., countries in the E.U., Canada and Australia since 2008 for treatment of OIC in advanced-illness patients receiving palliative care when laxative therapy has not been sufficient. Salix is responsible for further developing and commercializing Relistor, including completing clinical development necessary to support regulatory marketing approvals for potential new indications (such as chronic pain) and formulations of the drug, such as oral methylnaltrexone. Under our Agreement with Salix, we are eligible to receive (i) a development milestone of up to \$40 million upon U.S. marketing approval for subcutaneous Relistor in non-cancer pain patients (the proposed indication addressed in the Complete Response Letter mentioned above), (ii) a development milestone of up to \$50 million upon U.S. marketing approval of an oral formulation of Relistor, (iii) up to \$200 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 either marketing approval is subject to a Black Box Warning or Risk Evaluation and Mitigation Strategy (REMS), payment of a substantial portion of the milestone amount would be deferred, and subject, to achievement of the first commercialization milestone (payable on annual U.S. sales first exceeding \$100 million).

Salix has secured distribution for Relistor in the European territory and has licensed Link Medical Products Pty Limited for distribution in Australia, New Zealand, South Africa and certain other markets in Asia. Salix is continuing efforts to secure additional distribution partners and/or sublicensees in Europe and elsewhere.

Results of Operations (amounts in thousands unless otherwise noted)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Revenues	\$867	\$1,117	(22 %)	\$4,894	\$5,163	(5 %)
Expenses	(11,379)	(12,432)	(8 %)	(38,951)	(40,313)	(3 %)
Operating loss	(10,512)	(11,315)	(7 %)	(34,057)	(35,150)	(3 %)
Other income	12	14	(14 %)	36	43	(16 %)
Net loss	\$(10,500)	\$(11,301)	(7 %)	\$(34,021)	\$(35,107)	(3 %)

Revenues:

Our sources of revenue during the periods indicated below included our License Agreements with Salix, Ono and others and to a small extent research grants from the National Institutes of Health (NIH) and sales of research reagents.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Royalty income	\$719	\$728	(1 %)	\$3,052	\$4,181	(27 %)

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Collaboration revenue	145	136	7	%	1,512	521	190	%
Research grants	-	243	(100	%)	275	417	(34	%)
Other revenues	3	10	(70	%)	55	44	25	%
Total	\$867	\$1,117	(22	%)	\$4,894	\$5,163	(5	%)

Royalty income. During the three and nine months ended September 30, 2013 and 2012, respectively, we recognized \$719, \$3,052, \$728 and \$4,181 of royalty income based on the below net sales of Relistor reported by Salix, and net sales reported by Onalta™ licensee.



	Relistor Net Sales Reported by Collaborators			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
U.S.	\$3,700	\$3,800	\$17,100	\$25,100
Ex-U.S.	1,100	1,100	3,300	2,900
Global	\$4,800	\$4,900	\$20,400	\$28,000

Collaboration revenue. During the three and nine months ended September 30, 2013, we recognized \$145 and \$1,512, respectively, from upfront and reimbursement payments from partnering arrangements, compared to \$136 and \$521 in the 2012 periods. The balance of \$53 is recorded as deferred revenue – current.

Research grants. During the third quarters of 2013 and 2012, we recognized \$0 and \$243, respectively, and during the first nine months we recognized \$275 and \$417, respectively, as revenue from federal government grants by the NIH to support research and development programs. We do not expect to recognize revenue from the NIH in the future.

Other revenues, primarily from orders for research reagents, decreased to \$3 for the three months ended September 30, 2013, from \$10 for the same period in 2012 and increased to \$55 for the nine months ended September 30, 2013, from \$44 in 2012.

#### 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 \$8,077 for the three months ended September 30, 2013 from \$8,134 for the same period of 2012 and decreased to \$27,324 for the nine months ended September 30, 2013 from \$27,497 for the same period in 2012, as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Salaries and benefits	\$2,742	\$3,992	(31 %)	\$10,238	\$13,287	(23 %)

Three Months: Salaries and benefits decreased due to a decline in average headcount.

Nine Months: Salaries and benefits, including bonus expense, decreased due to a decline in average headcount, and reflecting a non-recurring retirement expense of \$1,804 incurred in the first quarter of 2012.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change

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Share-based compensation \$555 \$458 21 % \$2,136 \$4,036 (47 %)

Three Months: Share-based compensation increased from the 2012 period, primarily due to higher stock option expenses, partially offset by lower restricted stock expenses.

Nine Months: Share-based compensation decreased from the 2012 period, primarily due to lower equity incentives expenses, and reflecting non-recurring 2012 retirement-related option and restricted stock expense of \$1,638.

	Three Months Ended September 30,			Percent Change	Nine Months Ended September 30,			Percent Change
	2013	2012			2013	2012		
Clinical trial costs	\$2,798	\$882	217	%	\$6,117	\$1,961	212	%

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Three Months: Clinical trial costs increased primarily due to higher clinical trial expenses for Oncology (\$1,909) and Other programs (\$7).

Nine Months: Clinical trial costs increased primarily due to higher expenses for Oncology (\$4,199), partially offset by decreased expenses in Relistor (\$22) and Other programs (\$21).

	Three Months Ended September 30, 2013			Nine Months Ended September 30, 2013		
	2013	2012	Percent Change	2013	2012	Percent Change
Laboratory and manufacturing supplies	\$ 103	\$ 95	8 %	\$ 563	\$ 472	19 %

Three Months: Laboratory and manufacturing supplies increased by \$48 for Other programs, partially offset by lower expenses in Oncology (\$40), primarily from a decline in lab supplies due to suspension of our PI3K program.

Nine Months: Laboratory and manufacturing supplies increased by \$496 for Other programs, including second quarter impairment losses in connection with an amendment of the Company's Tarrytown lease, partially offset by lower Oncology expenses (\$405), primarily from a decline in lab supplies for PI3K and PSMA ADC.

	Three Months Ended September 30, 2013			Nine Months Ended September 30, 2013		
	2013	2012	Percent Change	2013	2012	Percent Change
Contract manufacturing and subcontractors	\$ 532	\$ 821	(35 %)	\$ 1,467	\$ 2,445	(40 %)

Three Months: Contract manufacturing and subcontractors decreased due to lower expenses for Oncology (\$141) and Other (\$147), primarily for the now-outlicensed C. difficile program.

Nine Months: Contract manufacturing and subcontractors decreased due to lower expenses for Oncology (\$535), Relistor (\$145) and Other (\$298), primarily for C. difficile.

	Three Months Ended September 30, 2013			Nine Months Ended September 30, 2013		
	2013	2012	Percent Change	2013	2012	Percent Change
Consultants	\$ 61	\$ 45	36 %	\$ 825	\$ 268	208 %

Three and Nine Months: Consultants expense increased due primarily to higher expenses for Oncology.

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	Three Months Ended September 30, 2013			Nine Months Ended September 30, 2013		
	2012	Percent Change		2012	Percent Change	
License fees	\$91	\$510	(82 %)	\$314	\$660	(52 %)

Three Months: License fees decreased due to lower expenses for Oncology (\$420).

Nine Months: License fees decreased due to lower expenses for Oncology (\$317) and Other programs (\$29).

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Royalty expense	\$ 73	\$ 73	0 %	\$ 308	\$ 420	(27 %)

Three Months: Royalty expenses remained unchanged at \$73 during the three month periods.

Nine Months: Royalty expenses were \$308 and \$420, respectively, during the nine month periods, due to a 2013 decrease in net sales of Relistor.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Other operating expenses	\$ 1,122	\$ 1,258	(11 %)	\$ 5,356	\$ 3,948	36 %

Three Months: Other operating expenses decreased from the 2012 period primarily due to decrease in rent (\$226), partially offset by increases in insurance (\$27), other operating expenses (\$23), travel (\$22) and facilities (\$18).

Nine Months: Other operating expenses increased from the 2012 period primarily due to increases in rent (\$1,357), resulting from lease amendment and termination expenses, other operating expenses (\$92), travel (\$66) and insurance (\$47), partially offset by a decrease in facilities (\$154).

General and Administrative Expenses decreased to \$3,123 for the three months ended September 30, 2013 from \$4,007 for the same period of 2012 and decreased to \$10,853 for the nine months ended September 30, 2013, from \$11,753 for the same period in 2012, as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Salaries and benefits	\$ 1,116	\$ 2,151	(48 %)	\$ 3,685	\$ 5,606	(34 %)

Three Months: Salaries and benefits decreased from the 2012 period due to a decline in average headcount.

Nine Months: Salaries and benefits, including bonus expenses, decreased from the 2012 period due to a decline in average headcount.

Three Months Ended September	Nine Months Ended September 30,
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	30,					
	2013	2012	Percent Change	2013	2012	Percent Change
Share-based compensation	\$248	\$496	(50 %)	\$767	\$1,714	(55 %)

Three and Nine Months: Share-based compensation decreased due to lower equity incentives expenses in the current periods as compared to the prior year, which included restructuring expenses in the third quarter.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Consulting and professional fees	\$664	\$475	40 %	\$3,064	\$1,579	94 %

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Three Months: Consulting and professional fees increased due to higher legal patent (\$121), legal (\$79), audit fee (\$20) and other fees (\$13), partially offset by a decrease in consulting expenses (\$44).

Nine Months: Consulting and professional fees increased due to higher consulting (\$659), legal patent (\$416), legal (\$316), audit fees (\$56) and other fees (\$38), primarily related to Molecular Insight acquisition transaction costs.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Other operating expenses	\$1,095	\$885	24 %	\$3,337	\$2,854	17 %

Three Months: Other operating expenses increased due to higher franchise taxes (\$40), investor relations (\$26), recruiting (\$19) and other operating expenses (\$209), partially offset by decreases in rent (\$74) and travel (\$10).

Nine Months: Other operating expenses increased due to higher expenses for recruiting (\$128), investor relations (\$123), taxes (\$88) and other operating expenses (\$242), partially offset by a decrease in rent (\$98).

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Depreciation and amortization	\$179	\$291	(38 %)	\$774	\$1,063	(27 %)

Three Months: Depreciation and amortization expense decreased to \$179 from \$291 for the 2012 period, primarily due to lower leasehold improvements and machinery and equipment fixed assets balances.

Nine Months: Depreciation and amortization expense decreased to \$774 from \$1,063 for the 2012 period, primarily due to lower leasehold improvements and machinery and equipment fixed assets balances.

Other income:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Percent Change	2013	2012	Percent Change
Interest income	\$12	\$14	(14 %)	\$36	\$43	(16 %)

Three and Nine Months: Interest income decreased from the 2012 period, due to lower average interest rates in 2013 than in 2012, partially offset by increases resulting from higher average balances of cash equivalents.

Income Taxes:

For the three and nine months ended September 30, 2013 and 2012 pre-tax losses were \$10,500, \$34,021, \$11,301 and \$35,107, respectively. We recognized a full tax valuation against deferred taxes at September 30, 2013 and December 31, 2012.

Net Loss:

Net loss was \$10,500 and \$34,021 for the three and nine months ended September 30, 2013, respectively, compared to \$11,301 and \$35,107 for the corresponding 2012 periods.

Liquidity and Capital Resources

We have to date funded operations principally through payments received from private placements of equity securities, public offerings of common stock, collaborations, grants and contracts, royalties, interest on investments, and proceeds from the exercise of outstanding options and warrants.



We received in 2013 a \$5,000 upfront payment from partnering of our C. difficile program and are eligible to receive future milestone and royalty payments. This receipt resulted in the reversal in 2013 of deferred tax assets and liabilities established in 2012 to reflect the net tax effects of temporary differences between the carrying amounts of certain assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

At September 30, 2013, we held \$75,597 in cash and cash equivalents, a decrease of \$3,624 from June 30, 2013, and an increase of \$16,759 from December 31, 2012. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. In addition, at September 30, 2013, our investment in auction rate securities classified as long-term assets on the Consolidated Balance Sheets amounted to \$2,208.

If we do not realize sufficient royalty or other revenue from Relistor or other collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on certain programs, and/or take other economic measures.

Cash used in operating activities for the nine months ended September 30, 2013 and 2012 was \$26,410 and \$28,914, respectively, due in each period to excess of expenditures on our research and development programs and general and administrative costs over cash received from collaborators and government grants.

#### Sources of Cash

**Operating Activities.** During the nine months ended September 30, 2013 we received \$8,896 under our collaborations, primarily consisting of (i) \$5,125 in upfront and reimbursement payments from partnering of our C. difficile program, (ii) \$3,213 in royalties and reimbursements from Salix, (iii) an upfront payment of \$189 from an Onalta™ out-license (iv) \$355 in reimbursement payments relating to our MIP-1404 product candidate, and (v) \$12 under the License Agreement with Ono. During the nine months ended September 30, 2012, we received \$5,078 under our collaborations, consisting of (i) \$323 in reimbursement payments under the Salix License Agreement, (ii) \$4,732 in royalties from Salix and (iii) \$23 under the License Agreement with Ono.

We have partially funded research programs through awards from the NIH. For the nine months ended September 30, 2013 and 2012, we received \$287 and \$431, respectively, of revenue from all of our NIH awards. We do not expect to recognize revenue from the NIH in the future.

We have no committed external sources of funding or capital other than agreements under which collaborators and licensees have contractual obligations to make payments to us. Other than revenues from Relistor, we expect no significant product revenues in the immediate or near-term future, as it will take a number of years to bring any of our current product candidates to the commercial marketing stage.

**Investing Activities.** Approximately 93% of our \$75,597 in cash and cash equivalents at September 30, 2013 was invested in money market funds. Our auction rate securities of \$2,208 consist of securities collateralized by student loan obligations subsidized by the U.S. government, \$1,100 of which was redeemed at par during the first and second quarters of 2013. 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. During the nine months ended September 30, 2013, we realized \$153 of proceeds from sales of fixed assets.

**Financing Activities.** During 2013, net cash provided by financing activities includes \$40,079 in net proceeds that we received for the issuance of 9.775 million shares of our common stock. In addition, during the nine months ended September 30, 2013 and 2012, we received cash of \$71 and \$196, respectively, from the exercise of stock options. 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.

Unless and until we obtain regulatory approval for additional product candidates and/or enter into agreements with corporate collaborators with respect to other proprietary assets, we will be required to fund our operations through sales of common stock or other securities or royalty or other financing arrangements. 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. Most of our cash is used to advance our research and development programs, including conducting pre-clinical studies and clinical trials, pursuing regulatory approvals for product candidates, filing and prosecuting patent applications and defending patent claims. Our expenses for research and development for the nine months ended September 30, 2013 and 2012 were \$27,324 and \$27,497, respectively. 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, 2013 and 2012, research and development costs incurred, by project, were as follows:

	Nine Months Ended September 30,	
	2013	2012
Oncology	\$26.1	\$23.5
Relistor	0.5	1.4
Other programs	0.7	2.6
Total	\$27.3	\$27.5

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

Investing Activities. During the nine months ended September 30, 2013 and 2012, we spent \$77 and \$759, 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 fixed and contingent payments under our licensing and collaboration agreements. The following table summarizes our contractual obligations as of September 30, 2013 for future payments under these agreements:

	Payments due by September 30,				
	Total (in millions)	2014	2015-2016	2017-2018	Thereafter
Operating leases	\$14.4	\$1.9	\$ 3.8	\$ 4.0	\$ 4.7
License and collaboration agreements:					
Fixed payments	1.4	0.4	0.4	0.5	0.1
Contingent payments (1)	90.1	0.1	2.4	9.0	78.6
Total	\$105.9	\$2.4	\$ 6.6	\$ 13.5	\$ 83.4

(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.

#### 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 more fully disclosed in Note 2 to our consolidated financial statements included in this quarterly report and Note 2 of our consolidated financial statements in our 2012 Annual Report on Form 10-K. 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 connection with the acquisition of Molecular Insight, we have established a policy for accounting for intangible assets, under which in process research and development and goodwill are initially measured at fair value and capitalized as an intangible asset and an impairment test for these intangibles is performed annually in the fourth quarter, unless impairment indicators require an earlier evaluation. Upon and subject to commercialization of the Company's product candidates, the IPR&D will be amortized over its estimated useful life. The estimated fair value of the contingent consideration liability is considered to be a Level 3 instrument and the Company reviews the fair value quarterly, or whenever events or circumstances occur that indicate a change in fair value.

There have been no other changes to our critical accounting policies and estimates as of and for the nine months ended September 30, 2013, which are disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2012 Annual Report on Form 10-K.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk (amounts in thousands unless otherwise noted)

Our primary investment objective is to preserve principal. Our money market funds and auction rate securities have interest rates that were variable and totaled \$72,563 at September 30, 2013. As a result, we do not believe that these investment balances have a material exposure to interest-rate risk.

At September 30, 2013, we continued to hold approximately \$2,208 (3.04% 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.

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. As a result of re-evaluating the valuation of these securities as of September 30, 2013, we reduced the temporary impairment amount to \$192 from \$260 at December 31, 2012. A 100 basis point increase in our internal analysis would result in a \$24 increase in the temporary impairment of these securities for the nine months ended September 30, 2013.

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#### 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 (CEO) and Principal Financial and Accounting Officer (PFO), as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, 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, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have a Disclosure Committee consisting of certain members of our senior management which monitors and implements our policy of disclosing material information concerning the Company in accordance with applicable law.

The Disclosure Committee, under the supervision and with the participation of senior management, including our CEO and PFO, 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 CEO and PFO concluded that our disclosure controls and procedures, as designed and implemented, 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 1. Legal Proceedings

As reported in our second quarter 2013 Quarterly Report on Form 10-Q and Note 10 to our interim Consolidated Financial Statements included in Part I, Item 1 of this Report, Progenics is a party to a proceeding brought by a former employee complaining that the Company violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating the former employee. The Company believes the former employee's claims are without merit and is contesting the matter vigorously. The federal District Court hearing the case issued in July an order denying our motion for summary judgment dismissing the former employee's complaint, making it likely that the proceeding will continue to trial. Given the inherent uncertainty attendant to the proceeding, it is not possible at this time to estimate the likelihood or potential magnitude of any outcome, and we have accordingly not recorded any associated liability in the interim Consolidated Financial Statements.

As disclosed in Note 1 to the interim financial statements included in this Report and in Part I, Item 2, MD&A, Progenics in October commenced an arbitration with Ono under the provisions of the parties' License Agreement for development and commercialization of subcutaneous Relistor in Japan, following a communication from Ono that it has determined to discontinue development because of "commercial concerns" that Ono contends would permit it to cease development and terminate the Agreement. Progenics is not in default under the Agreement, and Ono has neither asserted that Progenics is, nor terminated the Agreement. See Item 1A, Risk Factors.

#### Item 1A. Risk Factors

The future of our business and operations depends on the success of our Relistor collaborations and our oncology research and development programs, including the programs and product candidates of our Molecular Insight subsidiary.

Our business and operations entail a variety of serious risks and uncertainties and are inherently risky. The research and development programs on which we focus, including those of Molecular Insight, involve novel approaches to human therapeutics. Our product candidates are in pre-clinical or clinical development, and in some respects involve technologies with which we have limited prior experience. We are subject to the risks of failure inherent in the development of product candidates based on new technologies. 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 product candidates. We and our Relistor and other collaborators must successfully complete clinical trials and obtain regulatory approvals for potential commercial products. Once approved, if at all, commercial product sales are subject to general and industry-specific local and international economic pressures such as those experienced worldwide over the recent past. With our strategy to focus on oncology research and development, these risks continue to be significant and may increase to the extent the oncology space becomes more competitive or less favored in the commercial marketplace.



Our integration of Molecular Insight has required significant efforts, including coordination of research and development, as well as finance, accounting, and information technology and other functions, all of which involve expense and significant management time. The success of this acquisition will depend on, among other things, the strength of the product candidates of Molecular Insight and their underlying technologies; results of clinical trials, regulatory applications and approvals; and our ability to fund or otherwise develop acquired candidates and programs, achieve available cost savings, efficiencies and synergies, and attract and retain employees and consultants with expertise and experience appropriate to these efforts. In addition, the estimated fair values of the assets and liabilities acquired in the acquisition of Molecular Insight reflected in our financial statements do not, given the uniqueness of and uncertainties attendant to those assets and liabilities, reflect actual transactions or quoted prices and may not correlate to any future values or results. Such information should not be interpreted or relied upon as indicative of any future value or results. Our failure to manage successfully any of the product candidates, technologies or programs of Molecular Insight could have an adverse impact on our business, and on the price of our stock.

We are dependent on Salix, Ono and other business partners to develop and commercialize Relistor, exposing us to significant risks.

We 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 clinical trials and obtain regulatory approvals. We are and will be dependent upon Salix, Ono and any other business partners 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. Revenue from the sale of Relistor depends entirely upon the efforts of Salix and its sublicensees, which have significant discretion in determining the efforts and resources they apply 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 or formulations, marketing existing or future products or arranging for necessary sublicense or distribution relationships. Our business relationships with Salix, Ono and other partners may not be scientifically, clinically or commercially successful. For example, Salix has a variety of marketed products. Salix is not, however, a large diversified pharmaceutical company and does not have resources commensurate with such 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 revenue 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 or Ono, both of which have significantly greater financial and managerial resources which either could draw upon in the event of a dispute. Such disagreements 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. In addition, independent actions may be taken by Salix and/or Ono concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property, including, as discussed below, Relistor's path forward in light of the July 2012 Complete Response Letter from the FDA.

As noted elsewhere in this document, Progenics in October commenced an arbitration with Ono under the provisions of the parties' License Agreement for development and commercialization of subcutaneous Relistor in Japan, following a communication from Ono that it has determined to discontinue development because of "commercial concerns" that Ono contends would permit it to cease development and terminate the Agreement. Ono's discontinuation of development and/or protracted dispute resolution proceedings could result in reduced or delayed, or in the elimination of, milestone and/or royalty revenue from subcutaneous Relistor development in Japan. Under our License Agreement with Salix, in the event our Agreement with Ono terminates or rights thereunder otherwise revert to Progenics, the Salix Agreement automatically without payment by Salix extends to the license grants, territory and other rights provided in the Ono Agreement, as a result of which Salix and not Progenics would receive such rights.

As a result of the FDA's Complete Response Letter on Relistor for chronic pain, the Relistor program may be discontinued or otherwise at risk.

As previously announced, and noted elsewhere in this document, the FDA in July 2012 issued a Complete Response Letter in response to Salix's supplemental New Drug Application for Relistor for the treatment of OIC in adult patients with chronic, non-cancer pain. This development may result in Salix and/or Ono taking independent actions concerning product development, marketing strategies or other matters for Relistor, including termination of their efforts to develop and commercialize the drug. At an End-of-Review meeting in October 2012, the FDA's Division of Gastroenterology and Inborn Errors Products has expressed a concern that there may be a risk associated with the chronic use of mu-opioid antagonists in patients who are taking opioids for chronic pain, and, in order to understand this potential risk, the Division communicated that a very large, well-controlled, chronic administration trial will have to be conducted to assess the safety of any mu-opioid antagonist prior to market approval for the treatment of patients with OIC who are taking opioids for chronic, non-cancer pain. In addition, the FDA has informed Salix and Progenics that it will seek input from an Advisory Committee, which is expected to convene on March 10-11, 2014. For example, Salix has disclosed in regulatory filings that it might terminate its development program for Relistor subcutaneous injection for treatment of OIC in chronic non-cancer pain patients, and that additional information and additional guidance from the FDA could result in the termination of its oral OIC Relistor development program. As noted in our risk factor on regulatory approvals below, if clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, such as the concerns expressed in the FDA's CRL, we or our collaborators may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development programs for subcutaneous and/or oral Relistor for chronic, non-cancer pain patients may be significantly delayed or terminated altogether. In such an event, we could be faced with either further developing and commercializing the drug on our own or with one or more substitute collaborators, either of which paths would subject us to the development, commercialization, collaboration and/or financing risks discussed in these risk factors. Any such significant action adverse to development and commercialization of Relistor could have a material adverse impact on our business, and on the price of our stock.

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

Our business, products and product candidates 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 and product candidates. We cannot guarantee that approvals of product candidates, 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, such as a Risk Evaluation and Mitigation Strategy (REMS). For example, Relistor is only approved for OIC in patients with advanced illness and not for chronic, non-cancer pain.

If we or our collaborators violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we or they may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences. Under our license agreement with Salix, we are dependent on Salix for compliance with these regulatory requirements as they apply to Relistor. Salix has disclosed that in February it received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding its sales and promotional practices for Relistor and certain of its other products, that it is in the process of responding to the subpoena and intends to cooperate fully with the subpoena and related government investigation, that at the time of its disclosure it cannot predict or determine the timing or outcome of the inquiry or its impact on Salix's financial condition or results of operations, and that the laws and regulations regarding off-label promotion and the authorities' interpretation of them might increase its expenses, impair its ability to effectively market its products, and limit its revenue.

Our products may face regulatory, legal or commercial challenges even after approval.

Even if a product receives regulatory approval:

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

Approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are relatively less financially advantageous to us than approval of greater or different scope or subject to an FDA-imposed REMS that imposes limits on the distribution or use of the product.

Side effects identified after the product is on the market might hurt sales or result in mandatory safety labeling changes, additional pre-clinical testing or clinical trials, imposition of a REMS, product recalls or withdrawals from the market.

Efficacy or safety concerns regarding a marketed product, or manufacturing or other problems, may lead to a recall, withdrawal of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling, imposition of a REMS, the need for additional marketing applications, declining sales or other adverse events. These potential consequences may occur whether or not the concerns originate from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not they are scientifically justified. If products lose previously received marketing and other approvals, our business, results of operations and financial condition would be materially adversely affected.

We or our collaborators will be subject to ongoing FDA obligations and continuous regulatory review, and might be required to undertake post-marketing trials to verify the product's efficacy or safety or other regulatory obligations.

Developing product candidates will require us to obtain additional financing. Our access to capital funding is uncertain.

We expect to continue to incur significant development expenditures for our product candidates. We do not have committed external sources of funding for most of these projects. Our expenditures will be funded from cash on hand, or we may seek additional external funding for them, most likely through collaborative, license or royalty financing agreements with one or more pharmaceutical companies, equity securities issuances, debt financings, or government grants or contracts. To the extent we raise additional capital by issuing equity securities in the future, existing stockholders could experience substantial dilution in addition to the dilution experienced as a result of our recent equity offerings and the Molecular Insight acquisition, and new investors could have rights superior to existing stockholders if securities other than common stock were to be issued. Any debt financing that we are able to obtain may involve operating covenants that restrict our business and significant repayment obligations. To the extent that we raise additional funds through any new collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

We cannot predict when we will need additional funds, how much we will need, the form any financing may take or whether additional funds will be available at all, especially in light of current conditions in global credit and financial markets. Our need for future funding will depend on numerous factors, such as the availability of new product development projects; the achievement of events identified in our collaboration agreements that trigger payments to us from our collaboration partners, most of which are out of our control and rely entirely on the efforts of our partners; the progress and success of clinical trials and pre-clinical activities (including studies and manufacture of materials) of our product candidates conducted by our collaborators or us; the progress of research programs carried out by us; any changes in the breadth of our research and development programs; the progress of the research and development efforts of our collaborators; our ability to acquire or license other technologies or compounds that we seek to pursue; competing technological and market developments; the costs and timing of obtaining, enforcing and defending our patent and intellectual property rights; the costs and timing of regulatory approvals and filings by us and our collaborators; our ability to manage our growth; and any unforeseen litigation. These factors may be more important with respect to product candidates and programs that involve technologies with which we have limited prior experience, such as those originally developed by Molecular Insight. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or may adversely affect our ability to operate as a going concern. We may not be able at the necessary time to obtain additional funding on acceptable terms, or at all. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize our business.

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

Our ability to generate revenue in the near term depends on the timing of achievement, if any, of certain payment triggering events under our existing collaboration agreements and our ability to enter into additional collaboration agreements with third parties. We may not be successful in negotiating additional collaboration arrangements with pharmaceutical and biotechnology companies to develop and commercialize product candidates and technologies. If we do not enter into new collaboration arrangements, we would have to devote more of our resources to clinical product development and product launch activities and to seeking additional sources of capital to fund those activities. If we were not successful in seeking such capital, our cash burn rate would increase or we would need to take steps to reduce our rate of product development. Our ability to enter into new collaborations may be dependent on many factors, such as the results of clinical trials, competitive factors and the fit of our programs with the risk tolerance of a potential collaborator, including in relation to regulatory issues, the patent portfolio, the clinical pipeline, the stage of the available data, overall corporate goals and financial position. If we are not able to generate revenue under our collaborations when and in accordance with our expectations or the expectations of industry analysts, this failure could harm our business and have an immediate adverse effect on the trading price of our common stock.



Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure increases for our product candidates that are based on new technologies, as well as technologies with which we have limited prior experience, such as those originally developed by Molecular Insight. Pre-clinical studies and clinical trials are long, expensive and highly uncertain processes that can take many years. It will take us, or our collaborators, several years to complete clinical trials and the time required for completing testing and obtaining approvals is uncertain. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or our and our partners' financial constraints. The FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical trials, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. Results attained in early human clinical trials may not be indicative of results in later clinical trials. In addition, many of our investigational or experimental drugs are at an early stage of development, and successful commercialization of early stage product candidates requires significant research, development, testing and approvals by regulators, and additional investment. Our products in the research or pre-clinical development stage may not yield results that would permit or justify clinical testing. Our failure to demonstrate adequately the safety and efficacy of a product under development would delay or prevent marketing approval, which could adversely affect our operating results and credibility. The failure of one or more of our product candidates could have a material adverse effect on our business, financial condition and results of operations.

If we or our collaborators do not obtain regulatory approval for our product candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be adversely affected. Setbacks in clinical development programs could have a material adverse effect on our business.

Regulatory approvals are necessary to market product candidates and require demonstration of a product's safety and efficacy through extensive pre-clinical and clinical trials. We or our collaborators may not obtain regulatory approval for product candidates on a timely basis, or at all, and the terms of any approval (which in some countries includes pricing approval) may impose significant restrictions, limitations on use or other commercially unattractive conditions. We, our collaborators or regulators may also amend, suspend or terminate clinical trials if we or they believe that the participating subjects are being exposed to unacceptable health risks, and after reviewing trial results, we or our collaborators may abandon projects which we previously believed to be promising for commercial or other reasons unrelated to patient risks. During this process, we may find, for example, that results of pre-clinical studies are inconclusive or not indicative of results in human clinical trials, clinical investigators or contract research organizations do not comply with protocols or applicable regulatory requirements, or that product candidates do not have the desired efficacy or have undesirable side effects or other characteristics that preclude marketing approval or limit their potential commercial use if approved. In such circumstances, the entire development program for that product candidate could be adversely affected, resulting in delays in trials or regulatory filings for further marketing approval and a possible need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved. Conducting additional clinical trials or making significant revisions to a clinical development plan would lead to delays in regulatory filings. If clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, such as the concerns expressed in the FDA's July 2012 Complete Response Letter or during consideration of the oral Relistor development program, we or our collaborators may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development programs for subcutaneous and/or oral Relistor for chronic, non-cancer pain patients may be significantly delayed or terminated altogether.

Even if we agree to a path forward with Salix and the FDA, if the results of any future Relistor trials are not satisfactory or we or our collaborators encounter problems enrolling subjects, clinical trial supply issues, setbacks in developing drug formulations, including raw material-supply, manufacturing, stability or other difficulties, or issues complying with protocols or applicable regulatory requirements, the entire development program for Relistor could be adversely affected in a material manner. Such scenarios could also befall our other clinical-stage product candidates. If any of our collaborators breach or terminate its agreement with us or otherwise fail to conduct successfully and in a timely manner the collaborative activities for which they are responsible, the preclinical or clinical development or commercialization of the affected product candidate or research program could be delayed or terminated. We generally do not control the amount and timing of resources that our collaborators devote to our programs or product candidates. We also do not know whether current or future collaboration partners, if any, might pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases or conditions targeted by our collaborative arrangements. Setbacks of these types could have a material adverse effect on our business, results of operations and financial condition.



We or our collaborators must design and conduct successful clinical trials for our product candidates to obtain regulatory approval. We rely on third parties for conduct of clinical trials, which reduces our control over them and may expose us to conflicts of interest. Clinical trial results may be unfavorable or inconclusive, and often take longer than expected.

We have limited experience in conducting clinical trials, and we rely on or obtain the assistance of others to design, conduct, supervise or monitor some or all aspects of some of our clinical trials, including our ongoing phase 2 trials of PSMA ADC and MIP-1404. We have less control over the timing and other aspects of clinical trials for which we rely on third parties, such as CROs, clinical data management organizations, medical institutions or clinical investigators, than if we conducted them entirely on our own. These third parties may also have relationships with other entities, some of which may be our competitors. In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires us to comply with good clinical practices for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

To obtain regulatory approval of drug candidates, we must demonstrate through preclinical studies and clinical trials that they are safe and effective. Adverse or inconclusive clinical trial results concerning any of our drug candidates, or trials which regulators find deficient in scope, design or one or more other material respects, could require additional trials, resulting in increased costs, significant delays in submissions of approval applications, approvals in narrower indications than originally sought, or denials of approval, none of which we can predict. As a result, any projections that we publicly announce of commencement and duration of clinical trials are not certain. We have experienced clinical trial delays in the past as a result of slower than anticipated enrollment and such delays may recur. Delays can be caused by, among other things, deaths or other adverse medical events; regulatory or patent issues; interim or final results of ongoing clinical trials; failure to enroll clinical sites as expected; competition for enrollment from other clinical trials; scheduling conflicts with participating clinicians and institutions; disagreements, disputes or other matters arising from collaborations; our inability to obtain necessary funding; or manufacturing problems.

Under our license agreement, Salix generally has responsibility for conducting Relistor clinical trials, including all trials outside of the U.S. other than Japan, where Ono has the responsibility for 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. These arrangements expose us to the same considerations we face when contracting with third parties for our own trials.

Our product candidates may not obtain regulatory approvals needed for marketing.

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

Even if our product candidates obtain marketing approval, our ability to generate revenue will be diminished if our products are not accepted in the marketplace or our collaboration partners fail to obtain acceptable prices or an adequate level of reimbursement for products from third-party payors or government agencies.

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Market acceptance of approved products, such as Relistor for patients with advanced illnesses, is affected by the timing of regulatory approvals, product launches and

reimbursement programs for existing and expanded uses or generic, over-the-counter or other competitors; price increases for the product and relative prices of competing products; product development efforts for new indications; availability of sufficient commercial quantities of the product; success in arranging for necessary sublicense or distribution relationships; and general and industry-specific local and international economic pressures such as those experienced worldwide over the last five years. If health care providers believe that patients can be managed adequately with alternative, currently available therapies, they may not prescribe our products, especially if the alternative therapies are viewed as more effective, as having a better safety or tolerability profile, as being more convenient to the patient or health care providers or as being less expensive. Third-party insurance coverage may not be available to patients for any products we develop, alone or with collaborators. For pharmaceuticals administered in an institutional setting, the ability of the institution to be adequately reimbursed from government and health administration authorities, private health insurers and other third-party payors could also play a significant role in demand for our products. Significant uncertainty exists as to the reimbursement status of newly-approved pharmaceuticals. Government and other third-party payors increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for indications for which the FDA has not granted labeling approval. In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the U.S., we expect that there will continue to be a number of federal and state proposals to implement similar government control and that the emphasis on managed care in the U.S. will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that our collaborators receive for any products in the future and adversely affect the ability of our collaborators to commercialize our products and our realization of royalties from commercialization. If any of our products do not achieve market acceptance, we will likely lose our entire investment in that product.

Marketplace acceptance depends in part on competition in our industry, which is intense, and competing products in development may adversely affect acceptance of our products.

The extent to which any of our products achieves market acceptance will depend on competitive factors. Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. We face competition from many for-profit companies and major universities and research institutions in the U.S. and abroad. We face competition from companies marketing existing products or developing new products for diseases and conditions targeted by our technologies. We are aware of a number of products and product candidates, including ENTEREG® (alvimopan), AMITIZA® (lubiprostone), naloxegol, TARGIN® (oxycodone/naloxone), Zytiga® (abiraterone acetate), Xtandi® (enzalutamide), ProstaScint®, and Synergy Pharmaceuticals' SP-333, which compete or may potentially compete with Relistor, PSMA ADC or our other product candidates. For instance, there are product candidates in pre-clinical or clinical development that target the side effects of opioid pain therapy, and a marketed product for the treatment of post-operative ileus could compete with Relistor. We are aware of several competitors, including Janssen Biotech, Inc., Medivation, Inc./Astellas Pharma Inc., Algeta ASA, Jazz Pharmaceuticals, Dendreon Corp. and Bristol-Myers Squibb Co., which have received approval for or are developing alternative treatments or diagnostics for castration-resistant prostate cancer, some of which are directed against PSMA, and others, including MedImmune/Auven Therapeutics' Spirogen, which are developing ADCs as oncology therapeutics. Any of these competing approved products or product candidates, or others which may be developed in the future, may achieve a significant competitive advantage relative to Relistor, PSMA ADC, MIP-1404 or any of our other product candidates.

Competition with respect to our technologies and products is based on, among other things, product efficacy, safety, reliability, method of administration, availability, price and clinical benefit relative to cost; timing and scope of regulatory approval; sales, marketing and manufacturing capabilities; collaborator capabilities; insurance and other reimbursement coverage; and patent protection. Competitive disadvantages in any of these factors could materially harm our business and financial condition. Many of our competitors have substantially greater research and development capabilities and experience and greater manufacturing, marketing, financial and managerial resources than we do. These competitors may develop products that are superior to those we are developing and render our products or technologies non-competitive or obsolete. Our products and product candidates under development may not compete successfully with existing products or product candidates under development by other companies, universities and other institutions. Drug manufacturers that are first in the market with a therapeutic for a specific indication generally obtain and maintain a significant competitive advantage over later entrants and therefore, the speed with which industry participants move to develop products, complete clinical trials, approve processes and commercialize products is an important competitive factor. If our product candidates receive marketing approval but cannot compete effectively in the marketplace, our operating results and financial position would suffer.

If we or our collaborators are unable to obtain sufficient quantities of the raw and bulk materials needed to make our product candidates or Relistor, development of our product candidates or commercialization of our approved product 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. 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. Our existing arrangements with suppliers for our other product candidates may not result in the supply of sufficient quantities of our product candidates needed to accomplish our clinical development programs, and we may not have the right and in any event do not currently have the capability to manufacture these products if our suppliers are unable or unwilling to do so. We currently arrange for 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.



Manufacturing resources could limit or adversely affect our ability to commercialize products.

We or our collaborators engage third parties to manufacture our approved product and product candidates. We or our collaborators 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. Under our license agreement with Salix, Salix is responsible for obtaining supplies of Relistor, including contracting with contract manufacturing organizations for supply of Relistor active pharmaceutical ingredient and subcutaneous and oral finished drug product. These arrangements may not be on terms that are advantageous and, as a result of our royalty and other interests in Relistor's commercial success, will subject us to risks that the counterparties may not perform optimally in terms of quality or reliability. In engaging third parties for these activities, we do not control many aspects of the manufacturing process, including compliance with current Good Manufacturing Practices (cGMP) and other regulatory requirements. In order to commercialize our product candidates successfully, we or our collaborators need to be able to manufacture or arrange for the manufacture of 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 product candidates may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available 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.

Failure of any manufacturer of Relistor or our product candidates to comply with applicable regulatory requirements could subject us to penalties and have a material adverse effect on supplies of our product or products candidates.

Third-party manufacturers are required to comply with cGMP or similar regulatory requirements outside of the U.S. If manufacturers of our product or product candidates cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they may not be able to obtain any required approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays of several years in obtaining approval for a product candidate. We do not control the manufacturing process and are completely dependent on our third-party manufacturing partners or contractors for compliance with the applicable regulatory requirements for the manufacture of Relistor and our product candidates. Manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMP and similar regulatory requirements. Failure of any manufacturer of Relistor or any of our product candidates to comply with applicable cGMP or other regulatory requirements could result in sanctions being imposed on our collaborators or us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of Relistor or such product candidate and have a material adverse impact on our business, financial condition and results of operations.

We are dependent on patents and other intellectual property rights.

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

We own or have direct or sub-licenses to a number of issued patents. We must obtain, maintain and enforce patent and other rights to protect our intellectual property. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There are many laws, regulations and judicial decisions that dictate and otherwise influence the manner in which patent applications are filed and prosecuted and in

which patents are granted and enforced, all of which are subject to change from time to time. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. In addition, we are aware of others who have patent applications or patents containing claims similar to or overlapping those in our patents and patent applications. Accordingly, patent applications owned by or licensed to us may not result in patents being issued. Even if we own or license a relevant issued patent, we may not be able to preclude competitors from commercializing drugs that may compete directly with one or more of our products or product candidates, in which event such rights may not provide us with any meaningful competitive advantage. For example, we and Salix have no patent protection outside the U.S. for subcutaneous Relistor, our approved product, although we do have regulatory data exclusivity which provides a competitive barrier to generic entry for limited periods of time. In the absence or upon successful challenge of patent protection, drugs may be subject to generic competition, which could adversely affect pricing and sales volumes of the affected products.

It is generally difficult to determine the relative strength or scope of a biotechnology or pharmaceutical patent position in absolute terms at any given time. The issuance of a patent is not conclusive as to its validity or enforceability, which can be challenged in litigation or via administrative proceedings. The license agreements from which we derive or out-license intellectual property provide for various royalty, milestone and other payment, commercialization, sublicensing, patent prosecution and enforcement, insurance, indemnification and other obligations and rights, and are subject to certain reservations of rights. While we generally have the right to defend and enforce patents licensed to or by us, either in the first instance or if the licensor or licensee chooses not to do so, we must usually bear the cost of doing so. Under our license agreement with Salix, Salix generally has the first right to control the defense and enforcement of our Relistor patents. With respect to Japan, Ono has certain limited rights to prosecute, maintain and enforce relevant intellectual property. We may incur substantial costs in seeking to uphold the validity of patents or to prevent infringement. If the outcome of a dispute or contest is adverse to us, third parties may be able to use our patented invention without payment to us. Third parties may also avoid our patents through design innovation.

Patents have a limited life and expire by law.

In addition to uncertainties as to scope, validity, enforceability and changes in law, patents by law have limited lives. Upon expiration of patent protection, our drug candidates and/or products may be subject to generic competition, which could adversely affect pricing and sales volumes of the affected products.

With regard to our Relistor-related intellectual property, the composition-of-matter patent for the active ingredient of Relistor, methylnaltrexone, was invented in the 1970's and has expired. The University, as well as Progenics and its collaborators, have extended the methylnaltrexone patent estate with additional patents and pending patent applications covering various inventions relating to the product. Salix has listed in the FDA Orange Book four U.S. patents relating to subcutaneous Relistor, which have expiration dates ranging from 2017 to 2030, and one patent (expiring in 2024) with Health Canada. A patent issued in September provides protection for oral methylnaltrexone until 2031.

With respect to PSMA ADC, currently issued patents comprising co-owned and in-licensed properties have expiration ranges of 2022 to 2023 in the U.S. and 2022 to 2026 ex-U.S. Corresponding patent applications (except for the U.S. patent expiring in 2023) are pending worldwide, which if issued would have expiration ranges from 2022 to 2029. We view all of these patents as significant. A U.S. patent which expired earlier this year was not directly related to, and is not used in or required for the manufacture, use or prospective commercialization of, the PSMA ADC product candidate.)

Owned and in-licensed properties relating to the MIP-1404 product candidate have expiration ranges of 2020 to 2029; we view as most significant the composition-of-matter patent on the compound, as well as <sup>99m</sup>Tc labeled forms, which expires in 2029. Additional U.S. patents are directed to various inventions relating to the product candidate, and corresponding patent applications are pending worldwide.

We depend on intellectual property licensed from third parties and unpatented technology, trade secrets and confidential information. If we lose any of these rights, including by failing to achieve milestone requirements or to satisfy other conditions, or if they or data embodying or relevant to them are compromised by disruptions or breaches of information or data security, our business, results of operations and financial condition could be harmed.

Most of our product candidates, including Relistor, incorporate intellectual property licensed from third parties. For example, PSMA ADC utilizes technology licensed to us from Sloan-Kettering Institute for Cancer Research, through Cytogen Corporation, and Seattle Genetics, Inc. We can lose the right to patents and other intellectual property licensed to us if the related license agreement is terminated due to a breach by us or otherwise. Our ability, and that of our collaboration partners, to commercialize products incorporating licensed intellectual property would be impaired if the related license agreements were terminated. In addition, we are required to make substantial cash payments, achieve milestones and satisfy other conditions, including filing for and obtaining marketing approvals and

introducing products, to maintain rights under our intellectual property licenses. Due to the nature of these agreements and the uncertainties of research and development, we may not be able to achieve milestones or satisfy conditions to which we have contractually committed, and as a result may be unable to maintain our rights under these licenses. If we do not comply with our license agreements, the licensors may terminate them, which could result in our losing our rights to, and therefore being unable to commercialize, related products.



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

Progenics and other businesses and organizations worldwide, and in particular technology-intensive activities such as biotechnology research and development, are increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to facilitate or perform basic research and development functions, business processes, internal and external communications, and other critical functions. Progenics relies on such systems for most aspects of its business. The size and complexity of computer, communications and other electronic networked data generation, storage and transfer systems make them potentially vulnerable to breakdown, malicious intrusion, computer viruses and data security breaches by unauthorized third parties, employees or others. Such events may permit unauthorized persons to access, misappropriate and/or destroy sensitive data and result in the impairment or disruption of important business processes, loss of trade secrets or other proprietary intellectual property or public exposure of personal information (including sensitive personal information) of employees, business partners, clinical trial patients, customers and others. Any of the foregoing could have a material adverse effect on our business, prospects, operating results, and financial condition.

If we do not achieve milestones or satisfy conditions regarding some of our product candidates, we may not maintain our rights under related licenses.

We are required to make substantial cash payments, achieve milestones and satisfy other conditions, including filing for and obtaining marketing approvals and introducing products, to maintain rights under our intellectual property licenses. Due to the nature of these agreements and the uncertainties of research and development, we may not be able to achieve milestones or satisfy conditions to which we have contractually committed, and as a result may be unable to maintain our rights under these licenses. If we do not comply with our license agreements, the licensors may terminate them, which could result in our losing our rights to, and therefore being unable to commercialize, related products.

If we infringe third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.

There may be patent or other intellectual property rights belonging to others that require us to alter our products, pay licensing fees or cease certain activities. If our products infringe patent or other intellectual property rights of others, the owners of those rights could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any action brought against us, and any license required under any rights that we infringe may not be available on acceptable terms or at all. We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, we are aware of other groups investigating PSMA or related compounds, monoclonal antibodies directed at PSMA and targets relevant to PSMA ADC, and methylnaltrexone and other peripheral opioid antagonists, and of patents held, and patent applications filed, by these groups in those areas. While the validity of these issued patents, patentability of these pending patent applications and applicability of any of them to our programs are uncertain, if asserted against us, any related patent or other intellectual property rights could adversely affect our ability to commercialize our products.

Research, development and commercialization of a biopharmaceutical often requires choosing between alternative development and optimization routes at various stages in the development process. Preferred routes depend on subsequent discoveries and test results and cannot be predicted with certainty at the outset. There are numerous third-party patents in our field, and we may need to obtain a license under a patent in order to pursue the preferred development route of one or more of our products or product candidates. The need to obtain a license would decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, we might have to pursue a less desirable development route or terminate the program altogether.

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

We rely 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 approved product and our product candidates. 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 have entered into agreements under which we are now dependent on Ono and Salix for the commercialization and development of Relistor. We may not be able to maintain our relationships with them, or establish new ones for Relistor or other product 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. Moreover, if third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or applicable protocols, our product candidates may not be approved for marketing and commercialization or such approval may be delayed. If that occurs, we or our collaborators will not be able, or may be delayed in our efforts, to commercialize our product candidates.

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.

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

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected. Under our license agreement with Salix, we are responsible for product liability claims arising out of clinical trials that were conducted under our supervision. We are indemnified by Salix under our license agreement with Salix for product liability exposure arising from its marketing and sales of Relistor, and maintain our own product liability insurance coverage in the amount of \$10.0 million per occurrence, subject to a deductible and a \$10.0 million annual aggregate limitation and other clinical trial or other insurance as required by contract and local laws. Pursuant to our transition agreement with Wyeth Pharmaceuticals, we released Wyeth from its indemnification responsibility for product liability exposure arising from its marketing and sales of Relistor. Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all, and may not be available to us at a reasonable cost in the future. Our current insurance coverage and indemnification arrangements may not be adequate to cover claims brought against us, and are in any event subject to the insuring or indemnifying entity discharging its obligations to us.

We handle hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. If we are involved in a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

Our research and development work and manufacturing processes involve the use of hazardous, controlled and radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure. We may be required to incur significant costs to comply with environmental laws and regulations in the future.

If we lose key management and scientific personnel on whom we depend, our business could suffer.

We are dependent upon our key management and scientific personnel, the loss of whom could require us to identify and engage qualified replacements, and could cause our management and operations to suffer in the interim. Competition for qualified employees among companies in the biopharmaceutical industry is intense. Future success in our industry depends in significant part on the ability to attract, retain and motivate highly skilled employees, which we may not be successful in doing.

Health care reform measures could adversely affect our operating results and our ability to obtain marketing approval of and to commercialize our product candidates.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. In the U.S., federal legislation has changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of legislation have decreased coverage and reimbursement. Though such legislation applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. More recent legislation is intended to broaden access to health insurance, further reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, and impose new taxes and fees on the health industry and additional health policy reforms. New laws impose significant annual fees on companies that manufacture or import branded prescription drug products, and contain substantial new compliance provisions, which in each case may affect our business practices with health care practitioners. Subject to federal and state agencies issuing regulations or guidance, it appears likely that new laws will continue to pressure pharmaceutical pricing, especially under the Medicare program, and may also increase regulatory burdens and operating costs. We cannot be sure whether additional legislative changes will be enacted, whether the FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Our and/or our collaborators' relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us or them to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Health care providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our or our collaborators' future arrangements with third-party payors and customers may expose us or them to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we or our collaborators market, sell and distribute our products that obtain marketing approval. Efforts to ensure that business arrangements comply with applicable health care laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our or our collaborators' business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If such operations are found to be in violation of any of these laws or other applicable governmental regulations, we or the collaborator may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of related operations. If physicians or other providers or entities involved with our products are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may adversely affect us.

We cannot rely on federal government grants and research contracts as a continuing source of funds.

Federal government grants and research contracts, in particular from the National Institutes of Health, have in the past generally been available for biotechnology research and development in various areas. Funds available under such grants or contracts, however, must be applied for, if awarded must be used to fund qualifying research and development programs specified in the application, and are subject to adjustment based on the results of periodic

audits. 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 changes due to budgetary constraints, policy changes and other factors. While we have been awarded such grants and contracts in the past, we do not currently have significant funding from such sources, and in any event cannot rely on them as a continuing source of funds.

Our future depends on the proper management of our current and future business operations, including those of Molecular Insight, and their associated expenses.

Our business strategy requires us to manage our business to provide for the continued development and potential commercialization of our proprietary and partnered product candidates. Our strategy also calls for us to undertake increased research and development activities and to manage an increasing number of relationships with partners and other third parties, while simultaneously managing the capital necessary to support this strategy. These tasks are significantly increased as a result of our acquisition of Molecular Insight. If we are unable to manage effectively our current operations and any growth we may experience, our business, financial condition and results of operations may be adversely affected. If we are unable to effectively manage our expenses, we may find it necessary to reduce our personnel-related costs through reductions in our workforce, which could harm our operations, employee morale and impair our ability to retain and recruit talent. Furthermore, if adequate funds are not available, we may be required to obtain funds through arrangements with partners or other sources that may require us to relinquish rights to certain of our technologies, products or future economic rights that we would not otherwise relinquish or require us to enter into other financing arrangements on unfavorable terms.

Progenics has a history of operating losses, as does Molecular Insight, which has also been reorganized under the U.S. Bankruptcy Code.

Progenics has incurred substantial losses throughout its history. A large portion of our revenue has historically consisted of upfront and milestone from licensing transactions. We have reported operating losses for the first nine months of 2013 and 2012 and while we reported operating income for 2011, as a result of a one-time upfront payment from Salix, the timing and amount of any similar transactions in the future is highly unpredictable and uncertain. Without upfront or other such payments, we operate at a loss, due in large part to the significant research and development expenditures required to identify and validate new product candidates and pursue our development efforts. Moreover, we have derived no significant revenue from product sales and have only in the last several years derived revenue from royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur net operating losses and negative cash flow from operations in the future, which could increase significantly if we expand our clinical trial programs and other product development efforts, including those attendant to the product candidates and programs originally developed by Molecular Insight. Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval for and then commercializing our product candidates, either alone or with others. We may not be able to develop and commercialize products beyond subcutaneous Relistor for OIC in patients with advanced illness. Our operations may not be profitable even if any of our other product candidates under development are commercialized.

Molecular Insight incurred net losses every year from its inception in 1997 and generated no significant revenue from product sales and only limited revenue from licenses. In December 2010, MIP Insight filed a voluntary petition in the United States Bankruptcy Court for the District of Massachusetts seeking relief under the provisions of Chapter 11 of the U.S. Bankruptcy Code (Case No. 10-23355). It operated its business and managed its properties as a debtor in possession under bankruptcy protection until emerging from bankruptcy in May 2011.

Our ability to use net operating losses to offset future taxable income is subject to certain limitations.

We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. The U.S. Internal Revenue Code limits the amount of taxable income that may be offset annually by NOL carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation, and our use of NOL carryforwards may be further limited as a result of any future equity transactions that result in an additional change of control.

Progenics' stock price has a history of volatility and may be affected by selling pressure, including in the event of substantial sales of Progenics stock by former Molecular Insight stockholders. You should consider an investment in

Progenics stock as risky and invest only if you can withstand a significant loss.

Our stock price has a history of significant volatility. It has varied between a high of \$11.34 and a low of \$1.41 in 2012 and between a high of \$6.47 and a low of \$2.53 during the first nine months of 2013. Factors that may have a significant impact on the market price of our common stock include the results of clinical trials and pre-clinical studies undertaken by us or others; delays, terminations or other changes in development programs; developments in marketing approval efforts, such as the FDA's July 2012 Complete Response Letter with respect to the sNDA for Relistor subcutaneous injection for the treatment of OIC in adult patients with chronic, non-cancer pain; developments in collaborator or other business relationships, particularly regarding Relistor, PSMA ADC or other significant products or programs; technological innovation or product announcements by us, our collaborators or our competitors; patent or other proprietary rights developments; governmental regulation; changes in reimbursement policies or health care legislation; safety and efficacy concerns about products developed by us, our collaborators or our competitors; our ability to fund ongoing operations; fluctuations in our operating results; and general market conditions. At times, our stock price has been volatile even in the absence of significant news or developments. The stock prices of biotechnology companies and securities markets generally have been subject to dramatic price swings in recent years, and financial and market conditions during that period have resulted in widespread pressures on securities of issuers throughout the world economy.



Our stockholders may be diluted, and the price of our common stock may decrease, as a result of future issuances of securities, exercises of outstanding stock options, or sales of outstanding securities.

We expect to issue additional common stock and options to purchase common stock, and may issue preferred stock, restricted stock units or securities convertible into or exercisable or exchangeable for our common stock, which would dilute existing investors and could lower the price of our common stock. Sales of substantial numbers of outstanding shares of common stock, including sales by former MIP stockholders of unregistered shares received in the acquisition, could also 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, such as our recent follow-on offerings under our existing shelf registration statement, which may be used to issue up to approximately an additional \$31.7 million of common stock and other securities before any underwriter discounts, commissions and offering expenses. We also have in place registration statements covering shares issuable pursuant to our equity compensation plans, and sales of our securities under them could cause the market price of our stock to decline. 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.

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

At September 30, our directors and executive officers together beneficially owned or controlled approximately six percent of our outstanding common shares, and our five largest other stockholders approximately forty percent. Should these parties choose to act alone or together, they could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could, among other things, have the effect of delaying or preventing a change in control of the Company, adversely affecting our stock price.

Anti-takeover provisions may make removal of our Board and/or management more difficult, discouraging hostile bids for control that may be beneficial to our stockholders.

Our Board is authorized, without further stockholder action, to issue from time to time shares of preferred stock in one or more designated series or classes. The issuance of preferred stock, as well as provisions in some outstanding stock options that provide for acceleration of exercisability upon a change of control, and Section 203 and other provisions of the Delaware General Corporation Law could make a takeover or the removal of our Board or management more difficult; discourage hostile bids for control in which stockholders may receive a premium for their shares; and otherwise dilute the rights of common stockholders and depress the market price of our stock.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
10.35(1)†	Collaboration Agreement, effective February 21, 2001, by and between Abgenix, Inc. and PSMA Development Company, LLC
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 Angelo W. Lovallo, Jr., Vice President, Finance and Treasurer (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 of the Chief Executive Officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document
(1)	Incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011; previously filed in and incorporated herein by reference to Exhibit 10.35 of Amendment No. 2 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2009 and inadvertently omitted from Exhibit Index to its Annual Report on Form 10-K for the year ended December 31, 2012.

† Confidential treatment granted as to certain portions omitted and filed separately with the Commission.

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 12, 2013 By: /s/ Angelo W. Lovallo, Jr.

Angelo W. Lovallo, Jr.

Vice President, Finance & Treasurer

(Principal Financial and Accounting Officer)