PROGENICS PHARMACEUTICALS INC
Form 10-Q
May 06, 2015

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 March 31, 2015
Or
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File No. 000-23143

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

Delaware	13-3379479
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

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

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

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 May 1, 2015, a total of 69,644,949 shares of common stock, par value $.0013 per share, were outstanding.

PROGENICS PHARMACEUTICALS, INC.

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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)

	March 31, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 108,430	$ 119,302
Accounts receivable, net	152	109
Other current assets	3,006	2,515
Total current assets	111,588	121,926
Fixed assets, at cost, net of accumulated depreciation and amortization	2,473	2,552
Intangible assets, net (Note 4)	28,700	28,700
Goodwill	7,702	7,702
Other assets	157	157
Total assets	$ 150,620	$ 161,037
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,301	$ 6,570
Other current liabilities	115	115
Total current liabilities	5,416	6,685
Contingent consideration liability	17,500	17,200
Deferred tax liability – long term	11,332	11,332
Other liabilities	899	911
Total liabilities	35,147	36,128
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $.001 par value; 20,000,000 shares authorized; issued and outstanding – none	-	-
Common stock, $.0013 par value; 160,000,000 shares authorized; issued – 69,844,949 in 2015 and 69,832,949 in 2014	91	91
Additional paid-in capital	590,644	589,826
Accumulated deficit	(472,521)	(462,267)
Treasury stock, at cost (200,000 shares in 2015 and 2014)	(2,741)	(2,741)
Total stockholders' equity	115,473	124,909
Total liabilities and stockholders' equity	$ 150,620	$ 161,037

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

PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended March 31,	
	2015	2014
Revenues:		
Royalty income	$174	$735
Collaboration revenue	65	1,049
Other revenues	9	31
Total revenues	248	1,815
Expenses:		
Research and development	6,463	6,919
License fees – research and development	(16)	90
Royalty expense	42	82
General and administrative	3,593	3,405
Depreciation and amortization	132	144
Change in contingent consideration liability	300	500
Total expenses	10,514	11,140
Operating loss	(10,266)	(9,325)
Other income:		
Interest income	12	12
Total other income	12	12
Net loss	$(10,254)	$(9,313)
Net loss per share – basic and diluted	$(0.15)	$(0.15)
Weighted-average shares – basic and diluted	69,637	63,958

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 March 31,	
	2015	2014
Comprehensive loss	$(10,254)	$(9,313)

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

PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS ENDED MARCH 31, 2015 AND 2014

(amounts in thousands)
(Unaudited)

	Common Stock		Additional Paid-In		Accumulated Other Comprehensive	Treasury Stock		
	Shares	Amount	Capital	Accumulated Deficit	Income (Loss)	Shares	Amount	Total
Balance at December 31, 2014	69,833	$ 91	$589,826	$(462,267)	$ -	(200)	$(2,741)	$124,909
Net loss	-	-	-	(10,254)	-	-	-	(10,254)
Compensation expenses for share-based payment arrangements	-	-	757	-	-	-	-	757
Exercise of stock options	12	-	61	-	-	-	-	61
Balance at March 31, 2015	69,845	$ 91	$590,644	$(472,521)	$ -	(200)	$(2,741)	$115,473

	Common Stock		Additional Paid-In		Accumulated Other Comprehensive	Treasury Stock		
	Shares	Amount	Capital	Accumulated Deficit	Income (Loss)	Shares	Amount	Total
Balance at December 31, 2013	61,025	$ 79	$548,510	$(466,677)	$ (192)	(200)	$(2,741)	$78,979
Net loss	-	-	-	(9,313)	-	-	-	(9,313)
Compensation expenses for share-based payment arrangements	-	-	773	-	-	-	-	773
Sale of common stock in public offering, net of underwriting discounts and commissions ($2,415) and offering expenses ($380)	8,750	12	37,443	-	-	-	-	37,455
Balance at March 31, 2014	69,775	$ 91	$586,726	$(475,990)	$ (192)	(200)	$(2,741)	$107,894

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 Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(10,254)	$(9,313)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	132	144
Gains on sales of fixed assets	(2)	(43)
Change in contingent consideration liability	300	500
Expenses for share-based compensation awards	757	773
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(43)	2,062
(Increase) in other current assets	(491)	(905)
(Increase) in other assets	-	(1)
(Decrease) in accounts payable and accrued expenses	(1,269)	(2,531)
(Decrease) in other liabilities	(12)	(1)
Net cash used in operating activities	(10,882)	(9,315)
Cash flows from investing activities:		
Capital expenditures	(53)	(10)
Proceeds from sales of fixed assets	2	46
Net cash (used in) provided by investing activities	(51)	36
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of underwriting discounts and commissions and offering expenses	-	37,455
Proceeds from the exercise of stock options	61	-
Net cash provided by financing activities	61	37,455
Net (decrease) increase in cash and cash equivalents	(10,872)	28,176
Cash and cash equivalents at beginning of period	119,302	65,860
Cash and cash equivalents at end of period	$108,430	$94,036

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. (the Company, Progenics, we or us) develops innovative medicines for oncology. Our clinical development efforts center on later-stage oncology assets. We have completed phase 2 clinical trials of our therapeutic candidate for prostate cancer, PSMA ADC, a fully human monoclonal antibody-drug conjugate (ADC), and 1404 (trofolastat), an imaging agent candidate also for prostate cancer. We resumed a pivotal phase 2 clinical trial of Azedra™, our ultra-orphan radiotherapy candidate for pheochromocytoma. We are moving forward with MIP-1095 into clinical development and plan to file an Investigational New Drug (IND) application in the U.S.

On April 1, 2015, Valeant Pharmaceuticals International, Inc. acquired Salix Pharmaceuticals, Ltd., and Salix became a wholly-owned subsidiary of Valeant (references hereinafter to "Valeant" refer to Salix and Valeant as a consolidated entity as a result of the acquisition). We have licensed to Valeant our first commercial drug Relistor® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation (OIC), which in September 2014 received an expanded approval from the U.S. Food and Drug Administration (FDA) for the treatment of OIC in patients taking opioids for chronic non-cancer pain, and we expect an upcoming U.S. New Drug Application (NDA) filing for the oral indication. Recently, Relistor received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency for the treatment of OIC in adults with chronic non-cancer pain. We have partnered other internally-developed or acquired compounds and technologies with third parties. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving 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 royalty, commercialization milestone and revenue-sharing payments from Valeant's Relistor operations. Royalty and milestone payments from Relistor depend on success in development and commercialization, which is dependent on many factors, such as Valeant's efforts, decisions by the FDA and other regulatory bodies, competition from drugs for the same or similar indications, and the outcome of clinical and other testing of Relistor.

We fund our operations to a significant extent from capital-raising. In the first quarter of 2014, we raised $37.5 million in an underwritten public offering of 8.75 million shares of common stock at a public offering price of $4.60 per share, and entered into an agreement with an investment bank under which we may sell from time to time up to $50 million of our stock.

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. Certain of our intellectual property rights are held by wholly owned subsidiaries. All of our operations are conducted at our facilities in Tarrytown, New York. We operate under a single research and development segment.

Funding and Financial Matters. At March 31, 2015 we held $108.4 million in cash and cash equivalents, a decrease of $10.9 million from $119.3 million at 2014 year-end. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We expect to require additional funding in the future, the availability of which is never guaranteed and may be uncertain. We expect that we may continue to incur operating losses for the foreseeable future.

Our interim Consolidated Financial Statements 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 2014 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. Certain amounts have been reclassified in prior periods' financial statements to conform to the current year presentation. This includes the reclassification of (i) certain expenses for share-based compensation from research and development to general and administrative expenses and (ii) certain non-cash items from general and administrative expenses to change in contingent consideration liability, which reclassifications had no effect on total expenses as previously reported.

PROGENICS PHARMACEUTICALS, INC.

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

2. 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) of the Securities and Exchange Commission (SEC) 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. We recognize revenue for payments that are contingent upon performance solely by our collaborator immediately upon the achievement of the defined event if we have no related performance obligations. 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 to our revenue recognition accounting policies in the first quarter of 2015. These policies are disclosed in Note 2 to the consolidated financial statements included in our 2014 Annual Report on Form 10-K.

Under our 2012 agreement with FUJIFILM RI Pharma Co., Ltd. (Fuji) for the development of 1404 in Japan, we recognized as revenue a $1.0 million payment contingent on execution of the first contract by Fuji with an investigation site for a phase 1 trial in the first quarter of 2014.

3. Net Loss Per Share

Our basic net loss per share amounts have been computed by dividing net loss by the weighted-average number of common shares outstanding during the period. For each of the periods presented below, we reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. The calculations of net loss per share, basic and diluted, are as follows:

	Net Loss (Numerator)	Weighted Average Common Shares (Denominator) (in thousands)	Per Share Amount
Three months ended March 31, 2015			
Basic and diluted	$ (10,254)	69,637	$ (0.15)
Three months ended March 31, 2014			
Basic and diluted	$ (9,313)	63,958	$ (0.15)

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

	Three Months Ended March 31,			
	2015		2014	
	Number (in thousands)	Weighted Average Exercise Price	Number (in thousands)	Weighted Average Exercise Price

Options	6,259	$ 10.06	5,868	$ 10.74
Contingent consideration liability	2,781		3,168	
Total	9,040		9,036	

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)
(dollar amounts in thousands, except per share amounts or as otherwise noted)
4. In-Process Research and Development and Goodwill

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 impairment loss 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 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 fair value of the reporting unit (the Company has determined that it has only one reporting unit for this purpose), calculated as the product of shares outstanding and the share price as of the end of a period, to its carrying value (for this purpose, the Company's total stockholders' equity). No goodwill impairment has been recognized as of March 31, 2015 or 2014.

The following tables summarize the activity related to the Company's goodwill and indefinite lived IPR&D:

	Goodwill	IPR&D
Balance at January 1, 2015	$ 7,702	$28,700
Impairment	-	-
Balance at March 31, 2015	$ 7,702	$28,700

	Goodwill	IPR&D
Balance at January 1, 2014	$ 7,702	$31,360
Impairment	-	-
Balance at March 31, 2014	$ 7,702	$31,360

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – continued (unaudited)
(dollar amounts in thousands, except per share amounts or as otherwise noted)
5. Fair Value Measurements

We record the contingent consideration liability resulting from the Molecular Insight Pharmaceuticals, Inc. (MIP) acquisition at fair value in accordance with ASC 820-10-50.

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

		Fair Value Measurements at March 31, 2015		
	Balance at March 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$102,818	$102,818	$ -	$ -
Total Assets	$102,818	$102,818	$ -	$ -
Liability:				
Contingent consideration	$17,500	$-	$ -	$ 17,500
Total Liability	$17,500	$-	$ -	$ 17,500

		Fair Value Measurements at December 31, 2014		
	Balance at December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$112,808	$112,808	$ -	$ -
Total Assets	$112,808	$112,808	$ -	$ -
Liability:				
Contingent consideration	$17,200	$-	$ -	$ 17,200
Total Liability	$17,200	$-	$ -	$ 17,200

PROGENICS PHARMACEUTICALS, INC.

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

The estimated fair value of the contingent consideration liability of $17,500 as of March 31, 2015, 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 records the contingent consideration liability at fair value with changes in estimated fair values recorded in change in contingent consideration liability in the Consolidated Statements of Operations.

The following table presents quantitative information pertaining to the March 31, 2015 fair value measurement of the Level 3 inputs. The assumptions remained unchanged since December 31, 2014:

	Fair Value as of March 31, 2015	Fair Value as of December 31, 2014	Valuation Technique	Unobservable Input	Range (Weighted Average)
Contingent consideration liability:					
Azedra commercialization	$2,400	$ 2,300	Probability adjusted discounted cash flow model	Probability of success	40%
				Period of milestone expected achievement	2018
				Discount rate	10%
1404 commercialization	$3,900	$ 3,800	Probability adjusted discounted cash flow model	Probability of success	59%
				Period of milestone expected achievement	2019
				Discount rate	10%
MIP-1095 commercialization	$400	$ 400	Probability adjusted discounted cash flow model	Probability of success	19%
				Period of milestone expected achievement	2023
				Discount rate	10%
Net sales targets	$10,800	$ 10,700	Monte-Carlo simulation	Probability of success	19% - 59% (37.4%)

Period of milestone expected achievement	2019 - 2026
Discount rates [1]	12%/3.5%

[1] At March 31, 2015 and December 31, 2014, net sales targets contingent consideration liability was derived from a model under a risk neutral framework resulting in the application of 12% and 3.5% discount rates to estimated cash flows.

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, the following table summarizes the activities for the periods indicated:

Description	Liability – Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended March 31, 2015	2014
Balance at beginning of period	$17,200	$$15,700
Fair value change to contingent consideration included in net loss	300	500
Balance at end of period	$17,500	$16,200
Changes in unrealized gains or losses for the period included in earnings (or changes in net assets) for liabilities held at the end of the reporting period	$300	$$500

6. Accounts Receivable

Our accounts receivable represent amounts due to Progenics from collaborators, royalties and sales of research reagents, and at the below dates consisted of the following:

	March 31, 2015	December 31, 2014
Collaborators	$ 64	$ 14
Royalties	44	40
Other	54	65
	162	119
Less, allowance for doubtful accounts	(10)	(10)
Total	$ 152	$ 109

PROGENICS PHARMACEUTICALS, INC.

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

7. 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 at the below dates consisted of the following:

	March 31, 2015	December 31, 2014
Accrued consulting and clinical trial costs	$1,992	$ 2,662
Accrued payroll and related costs	666	1,722
Legal and professional fees	1,333	1,063
Accounts payable and other	1,310	1,123
Total	$5,301	$ 6,570

8. Commitments and Contingencies

In the ordinary course of our business, we enter into agreements with third parties, such as business partners, clinical sites and suppliers, that include 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 frequently not limited. We have not incurred material costs to defend lawsuits or settle claims related to these provisions. As a result, the estimated fair value of liabilities relating to indemnification provisions is minimal. We have no liabilities recorded for these provisions as of March 31, 2015 and December 31, 2014.

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 2013 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 uncertainty attendant to the proceeding, we have accrued amounts in connection with this matter which are not material to these Consolidated Financial Statements.

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; the sales of products by our partners and the royalty generated thereby; 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. We have completed phase 2 clinical trials of two product candidates for prostate cancer, and resumed a pivotal phase 2 trial of an ultra-orphan radiotherapy candidate for pheochromocytoma. We are moving forward with

MIP-1095 into clinical development, and plan to file an IND application in the U.S.

On April 1, 2015, Valeant Pharmaceuticals International, Inc. acquired Salix Pharmaceuticals, Ltd., and Salix became a wholly-owned subsidiary of Valeant (references hereinafter to "Valeant" refer to Salix and Valeant as a consolidated entity as a result of the acquisition). We have licensed our first commercial drug Relistor® (methylnaltrexone bromide) to Valeant, and have partnered other internally-developed or acquired compounds and technologies with third parties. In September 2014, Relistor subcutaneous injection for the treatment of OIC received an expanded approval from the U.S. FDA for the treatment of OIC in patients taking opioids for chronic non-cancer pain, and we expect an upcoming U.S. NDA filing for the oral indication. Recently, Relistor received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency for the treatment of OIC in adults with chronic non-cancer pain. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving 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 royalty, commercialization milestone and revenue-sharing payments from Valeant's Relistor operations. Royalty and milestone payments from Relistor depend on success in development and commercialization, which is dependent on many factors, such as Valeant's efforts, decisions by the FDA and other regulatory bodies, competition from drugs for the same or similar indications and the outcome of clinical and other testing of Relistor.

We fund our operations to a significant extent from capital-raising. In the first quarter of 2014, we raised $37.5 million in an underwritten public offering of 8.75 million shares of common stock at a public offering price of $4.60 per share, and entered into an agreement with an investment bank under which we may sell from time to time up to $50 million of our stock.

Most of our expenditures are for research and development activities. During the first quarter of 2015, expenses for Oncology, primarily related to AZEDRA™, PSMA ADC and 1404 and to a lesser extent, MIP-1095 were $6.3 million compared to $6.4 million in 2014. Expenses for Relistor and other programs were $0.2 million compared to $0.7 million in 2014. We expect to incur significant development expenses for our product candidates as clinical trials progress.

At March 31, 2015, we held $108.4 million in cash and cash equivalents, a decrease of $10.9 million from $119.3 million at 2014 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 for the foreseeable 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.

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 and in the U.S. since 2014 for the treatment of OIC in patients with non-cancer pain. Valeant is responsible for further developing and commercializing Relistor, including completing clinical development necessary to support regulatory marketing approvals for potential new indications and formulations of the drug, such as oral methylnaltrexone. Under our agreement with Valeant, we received a development milestone of $40 million upon U.S. marketing approval for subcutaneous Relistor in non-cancer pain patients and are eligible to receive (i) a development milestone of up to $50 million upon U.S. marketing approval of an oral formulation of Relistor, (ii) up to $200 million of commercialization milestone payments upon achievement of specified U.S. sales targets, (iii) royalties ranging from 15 to 19 percent of net sales by Valeant and its affiliates, and (iv) 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) Valeant 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).

Valeant 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, and in the third quarter of 2014 entered into an agreement with Lupin Limited for distribution of Relistor in Canada.

Results of Operations (amounts in thousands unless otherwise noted)

	Three Months Ended March 31,			
	2015	2014	Percent Change	
Revenues	$248	$1,815	(86	%)
Expenses	(10,514)	(11,140)	(6	%)
Operating loss	(10,266)	(9,325)	10	%
Other income	12	12	0	%
Net loss	$(10,254)	$(9,313)	10	%

Revenues (amounts in thousands unless otherwise noted):

Sources of revenue during the periods indicated below included license and other agreements with Valeant and other collaborators and, to a small extent, sale of research reagents.

Sources of Revenue	Three Months Ended March 31, 2015	2014	Percent Change	
Royalty income	$174	$735	(76	%)
Collaboration revenue	65	1,049	(94	%)
Other revenues	9	31	(71	%)
Total	$248	$1,815	(86	%)

Collaboration revenue:

During the three months ended March 31, 2015, we recognized $65 from reimbursement payments from partnering arrangements, compared to $1,049 in the 2014 period from milestone and reimbursement payments.

Royalty income. During the periods presented below we recognized royalty income primarily based on the below net sales (losses) of Relistor reported by Valeant.

	Relistor Net Sales (Losses) Three Months Ended March 31,	
	2015	2014
U.S.	$(200)	$3,600
Ex-U.S.	1,100	1,200
Global	$900	$4,800

Valeant reported the above net sales (losses), resulting in royalty income of $140 and $723 for the first quarter of 2015 and 2014, respectively, and the year-over-year decrease reflects a short-term wholesaler inventory reduction initiative implemented last quarter by our collaborator. Our first quarter 2015 royalty income together with the royalty loss from net Relistor losses during the fourth quarter of 2014, resulted in an accrued royalty loss liability balance of $516 at March 31, 2015.

Other revenues, primarily from orders for research reagents, changed as shown in the Sources of Revenue table above.

Expenses (amounts in thousands unless otherwise noted):

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 $6,489 for the three months ended March 31, 2015 from $7,091 for the same period of 2014, as follows:

	Three Months Ended March 31,		
	2015	2014	Percent Change
Salaries and benefits	$2,336	$2,876	(19 %)

Salaries and benefits decreased primarily due to a decline in average headcount.

	Three Months Ended March 31,		
	2015	2014	Percent Change
Share-based compensation	390	$477	(18 %)

Share-based compensation decreased primarily due to lower stock option expenses.

	Three Months Ended March 31,		
	2015	2014	Percent Change
Clinical trial costs	$1,046	$1,642	(36 %)

Clinical trial costs decreased due to lower expenses for Oncology ($596), primarily related to PSMA ADC and 1404, partially offset by higher Azedra-related expenses.

	Three Months Ended March 31,			
	2015	2014	Percent Change	
Laboratory and manufacturing supplies and equipment	$42	$ 34	24	%

Laboratory and manufacturing supplies and equipment increased due to higher expenses for Relistor and other programs ($27), partially offset by lower expenses in Oncology ($19).

	Three Months Ended March 31,			
	2015	2014	Percent Change	
Contract manufacturing and subcontractors	$1,380	$662	108	%

Contract manufacturing and subcontractors increased primarily due to higher expenses for Oncology ($717), resulting from Azedra-related expenses.

Expenses in this category relate to the conduct of clinical trials, including manufacture by third parties of drug materials, testing, analysis, formulation and toxicology services, and vary as the timing and level of such services are required.

	Three Months Ended March 31,			
	2015	2014	Percent Change	
Consultants	$241	$195	24	%

Consultants expense increased primarily due to higher expenses for Relistor and other programs ($47).

Expenses in this category relate to monitoring ongoing clinical trials and reviewing data from completed trials including the preparation of filings and vary as the timing and level of such services are required.

	Three Months Ended March 31,		
	2015	2014	Percent Change

License fees	$(16)	$ 90	(118 %)

License fees decreased primarily due to lower expenses for Oncology including the reversal of a previous quarter overaccrual.

	Three Months Ended March 31,		
	2015	2014	Percent Change
Royalty expense	$42	$ 82	(49 %)

The decrease in royalty expense was due to lower net sales of Relistor in 2015.

	Three Months Ended March 31,		
	2015	2014	Percent Change
Other operating expenses	$1,028	$1,033	0 %

Other operating expenses decreased primarily due to lower insurance ($4), facilities ($4) and other operating expenses ($6), partially offset by higher expenses for travel ($9).

General and Administrative Expenses increased to $3,593 for the three months ended March 31, 2015 from $3,405 for the same period of 2014, as follows:

	Three Months Ended March 31,		
	2015	2014	Percent Change
Salaries and benefits	$1,138	$1,319	(14 %)

Salaries and benefits decreased primarily due to a decline in average headcount.

	Three Months Ended March 31,		
	2015	2014	Percent Change
Share-based compensation	$367	$296	24 %

Share-based compensation increased due to higher stock option expenses.

	Three Months Ended March 31,		
	2015	2014	Percent Change

Consulting and professional fees	$1,104	$852	30	%

Consulting and professional fees increased due to higher legal ($145), audit ($102) and consulting fees ($73), as compared to prior year, partially offset by lower legal patent ($57) and other fees ($11).

	Three Months Ended March 31,		
	2015	2014	Percent Change
Other operating expenses	$984	$938	5 %

Other operating expenses increased due to higher expenses for taxes ($29), recruiting ($27), travel ($15) and other operating expenses ($52), partially offset by a decrease in investor relations expenses ($77).

	Three Months Ended March 31,		
	2015	2014	Percent Change
Depreciation and amortization	$132	$144	(8 %)

Depreciation and amortization expense decreased primarily due to lower depreciation for machinery and equipment.

	Three Months Ended March 31,		
	2015	2014	Percent Change
Change in contingent consideration liability	$300	$500	(40 %)

The first quarter review of the contingent consideration liability fair value resulted in a $300 increase, from $17,200 to $17,500, which has been recorded as non-cash expense in the Consolidated Statements of Operations. The increase in contingent consideration liability was due to a decrease in the discount period.

Other income (amounts in thousands unless otherwise noted):

	Three Months Ended March 31,		
	2015	2014	Percent Change
Interest income	$12	$ 12	0 %

Interest income remained unchanged compared to the first quarter of 2014.

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Income Taxes (amounts in thousands unless otherwise noted):

For the three months ended March 31, 2015 and 2014, there was no provision for income taxes due to pre-tax losses for those periods.

Net Loss (amounts in thousands unless otherwise noted):

Our net loss was $10,254 for the three months ended March 31, 2015 compared to $9,313 for the same period of 2014.

Liquidity and Capital Resources (amounts in thousands unless otherwise noted)

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 the first quarter of 2014 a $1,000 milestone payment from partnering the 1404 program in Japan. We are also eligible to receive future milestone and royalty payments.

At March 31, 2015, we held $108,430 in cash and cash equivalents, a decrease of $10,872 from $119,302 at December 31, 2014. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year.

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 three months ended March 31, 2015 and 2014 was $10,882 and $9,315, respectively, due to excess of expenditures on our research and development programs and general and administrative costs over cash received from collaborators.

During the first quarter of 2014, we established a $150,000 replacement shelf registration statement which we used for our first quarter 2014 underwritten public offering of 8,750 shares of common stock at a public offering price of $4.60 per share, resulting in net proceeds of approximately $37,455. We may utilize this shelf registration for the issuance of up to approximately $110,000 of additional common stock and other securities, including up to $50,000 of our common stock under an agreement with an investment bank providing for at-the-market sales through the bank.

Sources of Cash (amounts in thousands unless otherwise noted)

Operating Activities. During the three months ended March 31, 2015 we received $44 under our collaborations, primarily consisting of $30 in royalties from our Onalta out-license and $14 in reimbursements from Valeant. During the three months ended March 31, 2014 we received $3,856 under our collaborations, primarily consisting of $2,856 in royalties and reimbursements from Valeant and $1,000 in milestone payments relating to 1404.

Changes in Accounts receivable and Accounts payable for the three months ended March 31, 2015 and 2014 resulted from the timing of receipts from Valeant, Fuji, other partnering transactions, and, principally in prior periods, Ono Pharmaceutical Co., Ltd., and the timing of payments made to trade vendors in the normal course of business.

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 significant time to bring any of our current product candidates to the commercial marketing stage.

Investing Activities. Approximately 95% of our $108,430 in cash and cash equivalents at March 31, 2015 was invested in money market funds. During the first quarter of 2015, we realized $2 of proceeds from sales of fixed assets.

Financing Activities. During the three months ended March 31, 2015, we received cash of $61 from the exercise of stock options. During the three months ended March 31, 2014, net cash provided by financing activities included $37,455 in net proceeds from the issuance of 8,750 shares of common stock. The amount of cash we receive from these sources fluctuates commensurate with headcount levels and changes in the common stock price on and after the grant date.

Unless 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 agreements. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us may seriously jeopardize the future success of our business.

Uses of Cash (amounts in thousands unless otherwise noted)

Operating Activities. The majority of our cash has been 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. 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 periods presented, research and development costs incurred, by project, were as follows:

	Three Months Ended March 31,	
	2015	2014
	(in millions)	
Oncology	$6.3	$6.4
Relistor and other programs	0.2	0.7
Total	$6.5	$7.1

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

Investing Activities. During the three months ended March 31, 2015 and 2014, we have spent $53 and $10, 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 licensing, collaboration and other agreements. The following table summarizes our contractual obligations as of March 31, 2015 for future payments under these agreements:

	Payments due by Period				
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
	(in millions)				
Operating leases	$11.6	$1.9	$4.0	$4.1	$ 1.6
License and collaboration agreements:					
Fixed payments	1.0	0.3	0.4	0.3	-
Contingent payments [1]	104.1	-	2.3	12.7	89.1
Total	$116.7	$2.2	$6.7	$17.1	$ 90.7

(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 disclosed in Note 2 to our consolidated financial statements included in our 2014 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.

There have been no changes to our critical accounting policies and estimates as of and for the three months ended March 31, 2015, which are disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2014 Annual Report on Form 10-K.

Recent Accounting Developments

In May 2014, the FASB issued ASU No. 2014-09, which provides a single model for revenue arising from contracts with customers and supersedes current revenue recognition guidance. This ASU provides that an entity should recognize revenue to depict transfers of promised goods or services to customers in amounts reflecting the consideration to which the entity expects to be entitled in the transaction by: (1) identifying the contract; (2) identifying the contract's performance obligations; (3) determining the transaction price; (4) allocating the transaction price to the performance obligations; and (5) recognizing revenue when or as the entity satisfies the performance obligations. The ASU will be effective for annual reporting periods beginning after December 15, 2016, including interim periods. In April 2015, the FASB proposed deferring the effective date by one year, for interim and annual reporting periods beginning after December 15, 2017. Early adoption will be permitted for annual reporting periods beginning after December 15, 2016 and interim periods therein. The guidance permits companies to apply the requirements either retrospectively to all prior periods presented or in the year of adoption through a cumulative adjustment. We are evaluating the prospective impact of the pending adoption of this ASU on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This ASU will explicitly require management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosure in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016, unless we adopt it earlier. The adoption of this ASU is not expected to have a material impact on our consolidated financial statements and consolidated notes to these statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary investment objective is to preserve principal. Our money market funds have interest rates that were variable and totaled $102.8 million at March 31, 2015. As a result, we do not believe that these investment balances have a material exposure to interest-rate risk.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the timelines 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 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.

As required by SEC Rule 13a-15(e), we carried out an evaluation, under the supervision and with the participation of senior management, including our CEO and PFO, 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 the foregoing, our CEO and

PFO concluded that our current 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, as such term is defined in the Exchange Act Rules 13a-15(f) and 15d-15(f) 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 previously reported and discussed in Note 8 to our interim Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report, Progenics is a party to a proceeding brought by a former employee on November 2, 2010 in the U.S. District Court for the Southern District of New York, complaining that the Company violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating the former employee. The former employee seeks reinstatement of his employment, compensatory damages and certain costs and fees associated with the litigation. 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 2013 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 uncertainty attendant to the proceeding, we have accrued amounts in connection with this matter which are not material to our interim Consolidated Financial Statements.

Item 1A. Risk Factors

Our business and operations entail a variety of serious risks and uncertainties, including those described in Item 1A of our 2014 Annual Report on Form 10-K, amended by the following:

Valeant Pharmaceuticals International, Inc. acquired all of Salix's outstanding common stock on April 1, 2015. The acquisition of Salix by Valeant may negatively affect our collaborative agreements with Salix entered into prior to the acquisition, and could have a material adverse effect on our business.

On April 1, 2015, Valeant acquired Salix, and Salix became a wholly-owned subsidiary of Valeant (references hereinafter to "Valeant" refer to Salix and Valeant as a consolidated entity as a result of the acquisition). We cannot predict how Valeant may view the utility and attractiveness of Relistor going forward. Valeant may choose to focus or pursue alternative products in a manner that results in a termination of, or reduction in, revenues to us. We cannot predict whether Valeant will determine to continue, seek to change or terminate our collaboration on Relistor in the future, or devote the same resources Salix previously dedicated to it. If Valeant were to terminate the collaboration, we would no longer receive milestone and royalty payments and would need to undertake development and commercialization of Relistor ourselves or through another collaboration or licensing arrangement. Any decision by Valeant not to perform under our existing agreements could have a material adverse effect on our business.

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

We rely on Valeant to complete development and obtain regulatory approvals for additional formulations of and indications for Relistor worldwide. We are and will be dependent upon Valeant and any other business partners with which we may collaborate in the future to perform and fund development, including clinical testing of Relistor, making related regulatory filings and manufacturing and marketing 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 Valeant and its sublicensees, which have significant discretion in determining the efforts and resources they apply to sales of Relistor. Valeant may not 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 Valeant and other partners may not be scientifically, clinically or commercially successful. Valeant 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. Valeant may also re-assess its existing collaboration agreements as part of the acquisition of Salix. Changes of this nature might also occur if Valeant were acquired or if there is a management change. We may have future disagreements with Valeant, which has significantly greater financial and managerial resources which it 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 Valeant concerning product development, marketing strategies, manufacturing and supply issues and rights relating to intellectual property.

The Relistor program continues to be subject to risk.

Future developments in the commercialization of Relistor may result in Valeant or any other business partner with which we may collaborate in the future taking independent actions concerning product development, marketing strategies or other matters, including termination of its efforts to develop and commercialize the drug.

Prior to the acquisition, Salix had previously disclosed in regulatory filings 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 factors on regulation and regulatory approvals, if clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, we or our collaborators may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development program for oral Relistor may in the future 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, may not lead to marketing approval for our product candidates, and can subject us to unanticipated limitations, restrictions, delays and fines.

Our business, products and product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries, and include the recently enacted Sunshine Act under the Patient Protection and Affordable Care Act. 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.

For example, as described in our 2014 Annual Report under Business – Clinical Trial Activities, in the phase 2 trial of one of our principal product candidates, PSMA ADC, investigators have reported SAEs, including two deaths, in the 2.5 mg/kg dosing group. Based on data currently available to us, the Company is continuing development of PSMA ADC, at 2.3 mg/kg dose, and has not determined what effects, if any, treatment-related SAEs reported to date or that may be reported in the future may have on the development of PSMA ADC going forward. If, however, we, together with or independently of investigators participating in our clinical trials, or regulators evaluating PSMA ADC were to determine that this candidate cannot safely be administered to patients with sufficient therapeutic effect, we may determine to attempt to reformulate or otherwise change the candidate and/or its administration to alleviate such concerns, which could result in costs and delays that could impair the value of the candidate. If such costs and delays were sufficiently large, we could determine to abandon the PSMA ADC program. Concerns about the safety and/or efficacy of PSMA ADC could also make it more difficult or impossible for us to enter into licensing, collaboration or other arrangements with third parties for further development and commercialization of PSMA ADC. Any of these possibilities could have material adverse effects on Progenics' business, its financial condition and/or the price of our stock.

Even if we obtain regulatory approval for a product candidate, 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. For example, while subcutaneous Relistor is approved for OIC both in patients with advanced illness and for those with chronic, non-cancer pain, other formulations of and/or indications for Relistor may be subject to those or other such limitations and restrictions. Approvals for other product candidates, if approved at all, may also be so limited or restricted.

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 Valeant, we are dependent on Valeant for compliance with these regulatory requirements as they apply to Relistor. Salix previously disclosed that in February 2013 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 continuing to respond to the subpoena and intends to cooperate fully with the subpoena and related government

investigation, which has and will continue to increase its legal expenses and might require management time and attention, and that at the time of its disclosure it cannot predict or determine the timing or outcome of the inquiry or its impact on its financial condition or results of operations. We cannot predict the possible impact, if any, of the inquiry on the consolidated financial condition or results of operations of Valeant, after the completed acquisition of Salix.

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

We are aware of a number of products and product candidates described in our 2014 Annual Report under Business – Competition which compete or may potentially compete with Relistor. On March 31, 2015, MOVANTIK™ (Naloxegol), an oral peripheral mu-opioid receptor antagonist for patients with OIC developed by a Nektar-AstraZeneca PLC collaboration, was launched in the United States. Any of these approved products or product candidates, or others which may be developed in the future may achieve a significant competitive advantage relative to Relistor, and, in any event, the existing or future marketing and sales capabilities of these competitors may impair Valeant's and/or other collaborators' ability to compete effectively in the market.

We are also aware of competitors, including those described in our 2014 Annual Report under Business – Competition, which are developing alternative treatments for disease targets to which our research and development programs are directed, any of which – or others which may be developed in the future – may achieve a significant competitive advantage relative to any product we may develop.

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 1404 and the resumed Azedra phase 2b trial. We have less control over the timing and other aspects of clinical trials for which we rely on third parties, such as contract research organizations, 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, Valeant generally has responsibility for conducting Relistor clinical trials, including all trials outside of the U.S. 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.

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 those described in our 2014 Annual Report under Business – Competition, which compete or may potentially compete with Relistor, PSMA ADC or our other product candidates. For instance, MOVANTIK™ (Naloxegol) was recently launched and 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 those described in our 2014 Annual Report under Business – Competition, which have received approval for or are developing alternative treatments or diagnostics for castration-resistant prostate cancer, some of which are directed against PSMA. 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, 1404, Azedra, MIP-1095 or 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.

Valeant may not be able to fulfill manufacturing obligations for Relistor, a key raw material for which grows in Tasmania, 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 Valeant, Valeant 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 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.

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. 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 Valeant, Valeant generally has the first right to control the defense and enforcement of our Relistor patents. 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 respect to PSMA ADC, currently issued composition-of-matter 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 as well as patent applications directed to methods of use (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.

Owned and in-licensed properties relating to the 1404 product candidate have expiration ranges of 2023 to 2030; we view as most significant the composition-of-matter patent on the compound, as well as technetium-99 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.

With regard to our Relistor-related intellectual property, the composition-of-matter patent for the active ingredient of Relistor, methylnaltrexone, was invented in the 1970s and has expired. The University of Chicago, from which we have in-licensed methylnaltrexone, 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. Valeant has listed in the FDA Orange Book five 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. Issued U.S. patents provide protection for the oral methylnaltrexone product until 2031.

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 Valeant for the commercialization and development of Relistor. We may not be able to maintain our existing relationships, 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 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 Valeant, we are responsible for product liability claims arising out of clinical trials that were conducted under our supervision. We are indemnified by Valeant under our license agreement with Valeant for product liability exposure arising from its supply, 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. In October 2009, we released our former collaborator, Wyeth Pharmaceuticals, 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.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	Statement re computation of ratio of earnings (loss) to combined fixed charges and preferred stock dividends.
31.1	Certification of Mark R. Baker, Chief Executive Officer of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of 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

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: May 6, 2015 By: /s/ Angelo W. Lovallo, Jr.
Angelo W. Lovallo, Jr.
Vice President, Finance & Treasurer
(Principal Financial and Accounting Officer)