PROGENICS PHARMACEUTICALS INC
Form 10-Q
November 07, 2016
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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, 2016
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)**

One World Trade Center, 47th Floor
New York, NY 10007
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (646) 975-2500

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

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

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

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

As of November 3, 2016, a total of 70,051,441 shares of common stock, par value $0.0013 per share, were outstanding.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

PROGENICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2016 (unaudited)	**December 31, 2015 (audited)**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 98,894	$ 74,103
Accounts receivable, net	3,942	3,543
Other current assets	3,776	5,639
Total current assets	106,612	83,285
Property and equipment, net	3,899	2,407
Intangible assets, net	30,634	30,793
Goodwill	13,074	13,074
Other assets	2,718	1,692
Total assets	**$ 156,937**	**$ 131,251**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,100	$ 332
Accrued expenses	12,696	9,212
Other current liabilities	26	185
Total current liabilities	13,822	9,729
Contingent consideration liability	20,200	18,800
Deferred tax liability	11,199	11,199
Other liabilities	685	862
Total liabilities	**45,906**	**40,590**

Commitments and Contingencies		
Stockholders’ equity:		
Preferred stock, $0.001 par value		
Authorized - 20,000 shares; issued and outstanding - none	-	-
Common stock, $0.0013 par value		
Authorized - 160,000 shares; issued - 70,251 shares in 2016 and 70,146 shares in 2015	91	91
Additional paid-in capital	596,979	594,511
Treasury stock at cost, 200 shares of common stock	(2,741)	(2,741)
Accumulated other comprehensive loss	(74)	(26)
Accumulated deficit	(483,369)	(501,379)
Total Progenics stockholders' equity	110,886	90,456
Noncontrolling interests	145	205
Total stockholders’ equity	**111,031**	**90,661**
Total liabilities and stockholders’ equity	**$ 156,937**	**$ 131,251**

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

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PROGENICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2016	**2015**	**2016**	**2015**
Revenue:				
Royalty income	$3,319	$1,208	$7,888	$3,155
Collaboration revenue	50,523	183	56,839	393
Other revenue	8	5	50	33
Total revenue	53,850	1,396	64,777	3,581
Operating expenses:				
Research and development	9,827	7,048	26,964	20,255
General and administrative	7,220	4,572	18,637	14,424
Change in contingent consideration liability	600	(200)	1,400	900
Total operating expenses	17,647	11,420	47,001	35,579
Operating income (loss)	36,203	(10,024)	17,776	(31,998)
Other income:				
Interest income	79	10	176	33
Total other income	79	10	176	33
Net income (loss)	36,282	(10,014)	17,952	(31,965)
Net income (loss) attributable to noncontrolling interests	(21)	-	(58)	-
Net income (loss) attributable to Progenics	**$36,303**	**$(10,014)**	**$18,010**	**$(31,965)**
Net income (loss) per share attributable to Progenics - basic	**$0.52**	**$(0.14)**	**$0.26**	**$(0.46)**
Weighted-average shares - basic	**70,013**	**69,705**	**69,970**	**69,663**
Net income (loss) per share attributable to Progenics - diluted	**$0.52**	**$(0.14)**	**$0.26**	**$(0.46)**
Weighted-average shares - diluted	**70,297**	**69,705**	**70,006**	**69,663**

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

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PROGENICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

(Unaudited)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2016	**2015**	**2016**	**2015**
Net income (loss)	$36,282	$(10,014)	$17,952	$(31,965)
Other comprehensive loss:				
Foreign currency translation adjustments	(10)	-	(50)	-
Comprehensive income (loss)	36,272	(10,014)	17,902	(31,965)
Comprehensive income (loss) attributable to noncontrolling interests	(21)	-	(60)	-
Comprehensive income (loss) attributable to Progenics	**$36,293**	**$(10,014)**	**$17,962**	**$(31,965)**

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

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PROGENICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(In thousands)

(Unaudited)

	Common Stock Number of Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Treasury Stock Number of Shares	Treasury Stock Cost	Noncontrolling Interests	Total Stockholders' Equity
Balance at December 31, 2015	70,146	$ 91	$ 594,511	$ (501,379)	$ (26)	(200)	$ (2,741)	$ 205	$ 90,661
Net income	-	-	-	18,010	-	-	-	(58)	17,952
Foreign currency translation adjustments	-	-	-	-	(48)	-	-	(2)	(50)
Stock-based compensation expense	-	-	1,958	-	-	-	-	-	1,958
Exercise of stock options	105	-	510	-	-	-	-	-	510
Balance at September 30, 2016	**70,251**	**$ 91**	**$ 596,979**	**$ (483,369)**	**$ (74)**	**(200)**	**$ (2,741)**	**$ 145**	**$ 111,031**

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

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PROGENICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2016	**2015**
Cash flows from operating activities:		
Net income (loss)	$17,952	$(31,965)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,860	398
Stock-based compensation expense	1,958	2,705
Gain on sale of fixed assets	(291)	(1)
Change in fair value of contingent consideration liability	1,400	900
Changes in assets and liabilities:		
Accounts receivable	(403)	(1,410)
Other current assets	1,875	(3,497)
Other assets	(1,027)	(1)
Accounts payable	770	1,796
Accrued expenses	3,498	1,461
Other current liabilities	(159)	
Other liabilities	(176)	(37)
Net cash provided by (used in) operating activities	27,257	(29,651)
Cash flows from investing activities:		
Purchases of property and equipment	(3,261)	(274)
Proceeds from sale of fixed assets	341	46
Net cash used in investing activities	(2,920)	(228)
Cash flows from financing activities:		
Proceeds from exercise of stock options	510	1,015
Net cash provided by financing activities	510	1,015
Effect of currency rate changes on cash and cash equivalents	(56)	-
Net increase (decrease) in cash and cash equivalents	24,791	(28,864)
Cash and cash equivalents at beginning of period	74,103	119,302
Cash and cash equivalents at end of period	**$98,894**	**$90,438**

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

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

Note 1. Summary of Significant Accounting Policies

Business

Progenics Pharmaceuticals, Inc. and its subsidiaries ("the Company," "Progenics," "we," or "us") develops innovative medicines for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA® and 1095), and imaging agents (1404 and PyL™) intended to enable clinicians and patients to accurately visualize and manage their disease. In April 2016, we entered into an agreement with a subsidiary of Bayer AG ("Bayer") granting Bayer exclusive worldwide rights to develop and commercialize products using our prostate specific membrane antigen ("PSMA") antibody technology in combination with Bayer's alpha-emitting radionuclides. In addition, as part of our acquisition of EXINI Diagnostics AB ("EXINI") in late 2015, we acquired the EXINI Bone BSI bone scan index product, which is approved for use in Europe, Japan, and the U.S. (though not yet available in the U.S.).

In February 2011, we licensed our first commercial drug, RELISTOR® (methylnaltrexone bromide) for the treatment of opioid induced constipation ("OIC"), to Salix Pharmaceuticals, Inc. (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc. ("Valeant")). On July 19, 2016, the U.S. Food and Drug Administration ("FDA") approved RELISTOR Tablets for the treatment of OIC in adults with chronic non-cancer pain, for which we received a $50 million development milestone payment from Valeant in the third quarter of 2016. 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, development and commercialization milestones, and sublicense revenue-sharing payments from Valeant relating to RELISTOR. Royalty and further 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.

Under the agreement with Bayer, we received an upfront payment of $4 million and could receive up to an additional $49 million in potential clinical and regulatory development milestones. We are also entitled to single digit royalties on net sales, and potential net sales milestone payments up to an aggregate total of $130 million. During the second quarter of 2016, we recognized collaboration revenue of $5 million, of which $4 million related to the upfront payment and $1 million related to the achievement of a preclinical development milestone. We determined that the exclusive rights of the license agreement had standalone value and, accordingly, we recognized revenue for the upfront payment immediately (upon receipt in April 2016).

We commenced principal operations in 1988, became publicly traded in 1997, and throughout have been engaged primarily in research and development efforts, establishing corporate collaborations and related activities. Certain of our intellectual property rights are held by wholly-owned subsidiaries. All of our U.S. operations are presently conducted at our headquarters in New York, and EXINI's operations are conducted at our facility in Lund, Sweden. We operate under a single research and development business segment.

Liquidity

At September 30, 2016, we had $98.9 million of cash and cash equivalents, an increase of $24.8 million from $74.1 million at December 31, 2015. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We have historically funded our operations to a significant extent from capital-raising and 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.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

Basis of Presentation

Our interim condensed 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 U.S. ("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 condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2015. 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 prior period amounts in our condensed consolidated financial statements have been reclassified to conform to the current period presentation. Accounts payable, which was historically combined with accrued expenses on our consolidated balance sheet, has been presented as a separate line item for all periods presented in these unaudited condensed consolidated financial statements.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Progenics as well as its wholly-owned and controlled subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

Each of our international subsidiaries generally considers their respective local currency to be their functional currency. Assets and liabilities of these international subsidiaries are translated into U.S. dollars at quarter-end exchange rates and revenues and expenses are translated at average exchange rates during the quarter and year-to-date period. Foreign currency translation adjustments for the reported periods are included in accumulated other comprehensive loss (“AOCL”) in our condensed consolidated statements of comprehensive income (loss), and the

cumulative effect is included in the stockholders' equity section of our condensed consolidated balance sheets. Realized gains and losses from currency exchange transactions are recorded in operating expenses in our condensed consolidated statements of operations and were not material to our consolidated results of operations for the three and nine months ended September 30, 2016 or 2015.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

Property and Equipment

Property and equipment is recorded at historical cost, net of accumulated depreciation and amortization of $0.7 million and $10.3 million as of September 30, 2016 and December 31, 2015, respectively. The following table summarizes our property and equipment (in thousands):

	September 30, 2016	**December 31, 2015**
Machinery and equipment	$ 920	$ 5,706
Leasehold improvements	1,390	5,027
Computer equipment	676	1,727
Furniture and fixtures	729	131
Construction in progress	858	87
Property and equipment, gross	4,573	12,678
Less - accumulated depreciation	(674)	(10,271)
Property and equipment, net	**$ 3,899**	**$ 2,407**

On December 31, 2015, in connection with our decision to relocate our headquarters, we entered into a lease (the "Lease") for approximately 26,000 square feet of office space located in New York. The term of the Lease commenced on August 1, 2016, the date we first occupied the leased premises. The Lease term expires on September 30, 2030, and we have an option to renew the term for an additional five years. The Lease contains customary default provisions that could result in the early termination of the Lease in the event the Company defaults under the terms and conditions of the Lease.

As a result of our decision to relocate our headquarters, on January 1, 2016, we revised the estimated useful lives of our leasehold improvements at the leased premises in Tarrytown, New York. The remaining amortization period of our leasehold improvements was shortened from 5 years (original lease expiring in December 2020) to 7 months (based on our relocation in August 2016). During the three and nine months ended September 30, 2016, we recognized incremental amortization expense of $0.1 and $1.2 million, respectively, related to our leasehold improvements. All of the fully depreciated property and equipment, including leasehold improvements, at our former leased premises in Tarrytown, New York were written off as of August 1, 2016.

On May 6, 2016, we entered into an assignment and assumption agreement with BMR-Landmark at Eastview LLC (the "Landlord") and Regeneron Pharmaceuticals, Inc. ("Regeneron") pursuant to which we assigned to Regeneron the amended and restated lease agreement dated as of October 28, 2009 between the Landlord and us for our former headquarters at 771 Old Saw Mill River Road, Tarrytown, New York.

Note 2. New Accounting Pronouncements

Recently Adopted

In September 2015, the FASB issued ASU No. 2015-16 ("ASU 2015-16"), *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*. The standard requires the acquirer in a business combination to recognize in the reporting period in which adjustment amounts are determined any adjustments to provisional amounts that are identified during the measurement period, calculated as if the accounting had been completed at the acquisition date. ASU 2015-16 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. We adopted this standard during the quarter ended March 31, 2016. The adoption had no impact on our consolidated results of operations, financial condition, or cash flows as presented. However, the future impact of ASU 2015-16 will be dependent on future acquisitions, if any.

Not Yet Adopted

In August 2016, the FASB issued ASU No. 2016-15 (“ASU 2016-15”), *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The standard provides guidance on eight (8) cash flow issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon bonds; (3) contingent consideration payments after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. ASU 2016-15 addresses how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017 with early adoption permitted. We do not expect the adoption of this new standard to have a material impact on our consolidated financial statements.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation (Topic 718)* ("ASU 2016-09"). The standard simplifies several aspects of accounting for stock-based payment transactions, including the accounting for income taxes, forfeitures, statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for reporting periods beginning after December 15, 2016; however, early adoption is permitted. We are currently evaluating the impact of this new standard on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). The standard requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. Additionally, ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early application is permitted for all entities. We are currently evaluating the impact of this new standard on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). The standard requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and separate presentation of financial assets and financial liabilities by measurement category and form of financial asset. Additionally, ASU 2016-01 eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments on the balance sheet. ASU 2016-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Other than an amendment relating to presenting in comprehensive income the portion of the total change in the fair value of a liability resulting from a change in instrument-specific credit risk (if the entity has elected to measure the liability at fair value), early adoption is not permitted. We are currently evaluating the impact of this standard 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* ("ASU 2014-15"). The standard 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. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements and consolidated notes to these financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). The standard 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 guidance permits companies to apply the requirements either retrospectively to all prior periods presented or in the year of adoption through a cumulative adjustment. ASU 2014-09 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted for annual reporting periods beginning after December 15, 2016 and interim periods therein. In 2016, the FASB issued several amendments to the standard, including principal versus agent considerations when another party is involved in providing goods or services to a customer and the process of identifying performance obligations. We are evaluating which transition approach to use and the impact of this standard on our consolidated financial statements. We do not intend to early adopt.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

Note 3. Business Acquisition

Acquisition of EXINI Diagnostics AB

On November 12, 2015, we acquired 92.45% of the outstanding shares of EXINI, a Lund, Sweden based leader in the development of advanced imaging analysis tools and solutions for medical decision support. EXINI's operations are included in our condensed consolidated financial statements beginning November 12, 2015, the date we acquired control. Through the end of the extended acceptance period of November 20, 2015, we acquired additional outstanding shares and, as of September 30, 2016, we own 96.81% of the voting shares of EXINI. We commenced a judicial process in Sweden for acquiring the remaining shares and EXINI was delisted and ceased to be publicly traded effective as of the close of trading on December 4, 2015.

Note 4. Net Income (Loss) Per Share

Our basic net income (loss) per share attributable to Progenics amounts have been computed by dividing net income (loss) attributable to Progenics by the weighted-average number of common shares outstanding during the period. For the three and nine months ended September 30, 2016, we reported net income, and the computation of diluted earnings per share is based upon the weighted-average number of our common shares and dilutive effect of stock options (determined using the treasury stock method). For the three and nine months ended September 30, 2015, we reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive.

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

	Net income (loss) attributable to Progenics	**Weighted-average shares outstanding**	**Per share**

	(Numerator)	(Denominator)	amount
Three months ended September 30, 2016			
Basic	$ 36,303	70,013	$ 0.52
Dilutive effect of stock options	-	284	
Diluted	$ 36,303	70,297	$ 0.52
Nine months ended September 30, 2016			
Basic	$ 18,010	69,970	$ 0.26
Dilutive effect of stock options	-	36	
Diluted	$ 18,010	70,006	$ 0.26
Three months ended September 30, 2015			
Basic and diluted	$ (10,014)	69,705	$ (0.14)
Nine months ended September 30, 2015			
Basic and diluted	$ (31,965)	69,663	$ (0.46)

The following table summarizes anti-dilutive common shares or common shares where performance conditions have not been met, that were excluded from the calculation of diluted net income (loss) per share (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Stock options	3,332	6,487	5,127	6,484
Contingent consideration liability	3,342	2,359	3,946	2,709
Total anti-dilutive securities	**6,674**	**8,846**	**9,073**	**9,193**

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

Note 5. Fair Value Measurements

To estimate the fair values of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access
Level 2 – Valuations for which all significant inputs are observable, either directly or indirectly, other than Level 1 inputs
Level 3 – Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

We believe the carrying amounts of our cash equivalents, accounts receivable, other current assets, other assets, accounts payable and accrued expenses approximated their fair values as of September 30, 2016 and December 31, 2015.

We record the contingent consideration liability resulting from our acquisition of Molecular Insight Pharmaceuticals, Inc. ("MIP") at fair value in accordance with Accounting Standards Codification ("ASC") 820 (Topic 820, *Fair Value Measurement*).

The following tables summarize each major class of our financial assets and liabilities measured at fair value on a recurring basis as of the dates indicated, classified by valuation hierarchy (in thousands):

		Fair Value Measurements at September 30, 2016		
	Balance at September 30, 2016	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	$ 97,293	$97,293	$ -	$ -
Total assets	**$ 97,293**	**$97,293**	**$ -**	**$ -**
Liabilities:				
Contingent consideration liability	$ 20,200	$-	$ -	$ 20,200
Total liabilities	**$ 20,200**	**$-**	**$ -**	**$ 20,200**

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

		Fair Value Measurements at December 31, 2015		
	Balance at December 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	$ 68,140	$68,140	$ -	$ -
Total assets	**$ 68,140**	**$68,140**	**$ -**	**$ -**
Liabilities:				
Contingent consideration liability	$ 18,800	$-	$ -	$ 18,800
Total liabilities	**$ 18,800**	**$-**	**$ -**	**$ 18,800**

The estimated fair value of the contingent consideration liability of $20.2 million as of September 30, 2016, represents future potential milestone payments to former MIP stockholders. We consider 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 are 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. We record the contingent consideration liability at fair value with changes in estimated fair values recorded in change in contingent consideration liability in our condensed consolidated statements of operations.

The following table summarizes quantitative information and assumptions pertaining to the fair value measurement of the Level 3 inputs at September 30, 2016 and December 31, 2015 (in thousands). The increase in the contingent consideration liability of $1.4 million during the nine months ended September 30, 2016 was primarily attributable to a reduction in the discount period.

	Fair Value at September 30, 2016	December 31, 2015	Valuation Technique	Unobservable Input	Range (Weighted-Average)	
Contingent Consideration Liability:						
AZEDRA commercialization	$2,700	$2,500	Probability adjusted discounted cash flow model	Probability of success	40%	
				Period of expected milestone achievement	2018	
				Discount rate	10%	
1404 commercialization	4,500	4,200	Probability adjusted discounted cash flow model	Probability of success	59%	
				Period of expected milestone achievement	2019	
				Discount rate	10%	
1095 commercialization	500	500	Probability adjusted discounted cash flow model	Probability of success	19%	
				Period of expected milestone achievement	2023	
				Discount rate	10%	
Net sales targets	12,500	11,600	Monte-Carlo simulation	Probability of success	19% - 59%	(37.4%) at September
				Period of expected	2019 - 2022	

			milestone achievement		30, 2016
				2019 - 2025	at December 31, 2015
			Discount rate[1]	11% / 4.2%	at September 30, 2016
				12% / 3.5%	at December 31, 2015
Total	**$20,200**	**$18,800**			

(1) The contingent consideration liability related to the net sales targets was derived from a model under a risk neutral framework resulting in the application of 11% and 4.2% at September 30, 2016 and 12% and 3.5% at December 31, 2015, discount rates to estimated cash flows.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

For those financial instruments with significant Level 3 inputs, the following tables summarize the activities for the periods indicated:

	Liability - Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended September 30,	
	2016	**2015**
Balance at beginning of period	$19,600	$18,300
Fair value change included in net loss	600	(200)
Balance at end of period	**$20,200**	**$18,100**
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	**$600**	**$(200)**

	Liability - Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Nine Months Ended

	September 30,	
	2016	**2015**
Balance at beginning of period	$18,800	$17,200
Fair value change included in net loss	1,400	900
Balance at end of period	**$20,200**	**$18,100**
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	**$1,400**	**$900**

Note 6. Accounts Receivable

Our accounts receivable represent amounts due to us from collaborators, royalties, and sales of research reagents, and consisted of the following at September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	**December 31, 2015**
Royalties	$ 3,319	$ 3,463
Collaborators	161	63
Other	462	27
Accounts receivable, gross	3,942	3,553
Less - Allowance for doubtful accounts	-	(10)
Accounts receivable, net	**$ 3,942**	**$ 3,543**

Note 7. Goodwill, In-Process Research and Development, and Other Intangible Assets

The fair values of in-process research and development ("IPR&D") and other identified intangible assets acquired in business combinations are capitalized. We utilize 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 or "replacement costs", whichever is greater. 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 IPR&D project and other identified intangible assets, independently. IPR&D 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. Other identified intangible assets, which include the technology asset acquired as part of the EXINI business combination, are amortized over the relevant estimated useful life. The IPR&D assets are tested for impairment at least annually or when a triggering event occurs that could indicate a potential impairment and any impairment loss is recognized in our condensed consolidated statements of operations.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

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. We determine whether goodwill may be impaired by comparing the fair value of the reporting unit (we have determined that we have 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, our total stockholders' equity). No goodwill impairment has been recognized as of September 30, 2016 or 2015.

The following tables summarize the activity related to our goodwill and intangible assets (in thousands):

	Goodwill	IPR&D	Other Intangible Assets
Balance at January 1, 2016	$ 13,074	$28,700	$ 2,093
Amortization expense	-	-	(159)
Impairment	-	-	-
Balance at September 30, 2016	**$ 13,074**	**$28,700**	**$ 1,934**

	Goodwill	IPR&D	Other Intangible Assets
Balance at January 1, 2015	$ 7,702	$28,700	$ -
Amortization expense	-	-	-
Impairment	-	-	-
Balance at September 30, 2015	**$ 7,702**	**$28,700**	**$ -**

Note 8. Accrued Expenses

The carrying value of our accrued expenses approximates fair value as it represents amounts that will be satisfied within one year. Accrued expenses consisted of the following at September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Loss contingency for litigation	$ 5,010	$ 2,516
Accrued legal and professional fees	1,091	1,089
Accrued consulting and clinical trial costs	2,908	2,844
Accrued payroll and related costs	2,040	1,961
Other	1,647	802
Accrued expenses	**$ 12,696**	**$ 9,212**

Note 9. Commitments and Contingencies

We are or may be from time to time involved in various other disputes, governmental and/or regulatory inspections, inquiries, investigations, and proceedings that could result in litigation, and other litigation matters that arise from time to time. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect us, our results of operations, financial condition, and cash flows.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

In each of the matters described in this filing or in *Note 10. Commitments and Contingencies* to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015, plaintiffs seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process (which in complex proceedings of the sort faced by us often extend for several years). As a result, none of the matters described in this filing, except for the former employee litigation, have progressed sufficiently through discovery and/or development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position, or cash flows.

Former Employee Litigation

We are 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 we had violated the anti-retaliation provisions of the Federal Sarbanes-Oxley law by terminating the former employee. The former employee sought reinstatement of his employment, compensatory damages, and certain costs and fees associated with the litigation. In July 2013, the Federal District Court hearing the case issued an order denying our motion for summary judgment dismissing the former employee's complaint. The case went to trial in July 2015 and, on July 31, 2015, the jury awarded the former employee approximately $1.7 million in compensatory damages (held in escrow by the District Court and recorded as restricted cash in other current assets on our condensed consolidated balance sheet) primarily consisting of salary the former employee would have received during the period from his termination to the date of the verdict. On August 30, 2016, the judge issued an opinion and awarded the former employee approximately $3.3 million for front pay compensation and pre-judgment interest. As a result, we recorded an additional accrual of $2.5 million in the three months ended September 30, 2016 related to this matter. At September 30, 2016, we had an aggregate amount of approximately $5.0 million accrued for this loss contingency deemed probable and estimable, which is included in accrued expenses on our condensed consolidated balance sheet. We have filed for an appeal.

Abbreviated New Drug Application Litigations

On October 7, 2015, Progenics, Valeant, and Wyeth LLC (Valeant's predecessor as licensee of RELISTOR) received notification of a Paragraph IV certification for certain patents for RELISTOR subcutaneous injection, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The

certification resulted from the filing by Mylan Pharmaceuticals, Inc. of an Abbreviated New Drug Application ("ANDA") with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

On October 28, 2015, Progenics, Valeant, and Wyeth LLC received a second notification of a Paragraph IV certification with respect to the same patents for RELISTOR subcutaneous injection from Actavis LLC as a result of Actavis LLC's filing of an ANDA with the FDA, also challenging these patents and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

In accordance with the Drug Price Competition and Patent Term Restoration Act (commonly referred to as the Hatch-Waxman Act), we and Valeant timely commenced litigation against each of these ANDA filers in order to obtain an automatic stay of FDA approval of the ANDA until the earlier of (i) 30 months from receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On October 25, 2016, we received a notification of a Paragraph IV certification with respect to certain patents for RELISTOR Tablets, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certification accompanied the filing by Actavis LLC of an ANDA challenging such patents for RELISTOR Tablets. We and our licensee for RELISTOR, Valeant, are assessing the notification and intend to vigorously enforce RELISTOR intellectual property rights.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

The ANDA notification and each of the ANDA litigation proceedings above are in their early stages and we and Valeant continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between us and Valeant, Valeant has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement.

In addition to the aforementioned ANDA notifications, in October 2015, we received notices of opposition to three European patents relating to methylnaltrexone. The oppositions were filed separately by each of Actavis Group PTC ehf. and Fresenius Kabi Deutschland GmbH.

Note 10. Stockholders' Equity

Common Stock and Preferred Stock

We are authorized to issue 160.0 million shares of our common stock, par value $0.0013, and 20.0 million shares of preferred stock, par value $0.001. The Board of Directors (the "Board") has the authority to issue common and preferred shares, in series, with rights and privileges as determined by the Board.

Shelf Registration

During the first quarter of 2014, we established a $150.0 million replacement shelf registration statement, which we used for our February 2014 underwritten public offering of 8.75 million shares of common stock at a public offering price of $4.60 per share, resulting in net proceeds of approximately $37.5 million. We may utilize this shelf registration for the issuance of up to approximately $110.0 million of additional common stock and other securities, including up to $50.0 million of our common stock under an agreement with an investment bank providing for at-the-market sales through the bank. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the U.S. Securities and Exchange Commission.

Accumulated Other Comprehensive Loss

The following table summarizes the components of AOCL at September 30, 2016 (in thousands):

	Foreign Currency Translation	AOCL
Balance at January 1, 2016	$ (26)	$ (26)
Foreign currency translation adjustment	(48)	(48)
Balance at September 30, 2016	**$ (74)**	**$ (74)**

We did not have any reclassifications out of AOCL to losses during the nine months ended September 30, 2016 or 2015.

Note 11. Stock-Based Compensation

Equity Incentive Plans

We adopted the following stockholder-approved equity incentive plans:

The 1996 Amended Stock Incentive Plan (the "1996 Plan") authorized the issuance of up to 5,000,000 shares of our common stock covering several different types of awards, including stock options, restricted shares, stock appreciation rights, performance shares, and phantom stock. The 1996 Plan was terminated in 2006. Options granted before termination of the 1996 Plan will continue to remain outstanding until exercised, cancelled, or expired.

The 2005 Stock Incentive Plan (the "2005 Plan"), pursuant to which we are authorized to issue up to 11,450,000 shares of common stock covering several different types of awards, including stock options, restricted shares, stock appreciation rights, performance shares, and phantom stock. The 2005 Plan will terminate on March 25, 2024.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

The stock option plans provide that options may be granted at an exercise price of 100% of fair market value of our common stock on the date of grant, may be exercised in full or in installments, at the discretion of the Board or its Compensation Committee (the "Compensation Committee"), and must be exercised within ten years from date of grant. Stock options generally vest pro rata over three to five years. We recognize stock-based compensation expense on a straight-line basis over the requisite service (vesting) period based on fair values. We use historical data to estimate expected employee behaviors related to option exercises and forfeitures and included these expected forfeitures as a part of the estimate of stock-based compensation expense as of the grant date. We adjust the total amount of stock-based compensation expense recognized for each award, in the period in which each award vests, to reflect the actual forfeitures related to that award. Changes in our estimated forfeiture rate will result in changes in the rate at which compensation cost for an award is recognized over its vesting period.

Stock Options

The following table summarizes stock options activity for the nine months ended September 30, 2016 (in thousands, except per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at January 1, 2016	5,134	$ 9.05	5.69
Granted	1,129	$ 4.60	
Exercised	(105)	$ 4.88	
Cancelled	(908)	$ 6.84	
Expired	(303)	$ 24.90	
Outstanding at September 30, 2016	**4,947**	**$ 7.55**	**5.97**
Exercisable at September 30, 2016	**3,634**	**$ 8.40**	**4.89**
Vested and expected to vest at September 30, 2016	**4,717**	**$ 7.67**	**5.82**

The weighted average fair value of options granted during the three and nine months ended September 30, 2016 was $3.68 and $3.13 per share, respectively and during the three and nine months ended September 30, 2015 was $6.56 and $5.04 per share, respectively.

The total intrinsic value (the excess of the market price over the exercise price) was approximately $3.9 million for stock options outstanding, $2.3 million for stock options exercisable, and $3.7 million for stock options vested and expected to vest as of September 30, 2016. The total intrinsic value for stock options exercised during the three and nine months ended September 30, 2016 was approximately $118 thousand and $119 thousand, respectively, and during the three and nine months ended September 30, 2015 was approximately $185 thousand and $231 thousand, respectively.

We do not expect to realize any tax benefits from our stock option activity or the recognition of stock-based compensation expense, because we currently have net operating losses and have a full valuation allowance against our deferred tax assets. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the nine months ended September 30, 2016 and 2015.

Stock-Based Compensation Expense

We account for stock-based awards issued to employees in accordance with the provisions of ASC 718 (Topic 718, *Compensation – Stock Compensation*). We recognize stock-based compensation expense on a straight-line basis over the service period of the award, which is generally three to five years. Stock-based awards issued to consultants are accounted for in accordance with the provisions of ASC 718 and ASC 505-50 (Subtopic 50 "Equity-Based Payments to Non-Employees" of Topic 505, *Equity*). Options granted to consultants are periodically revalued as the options vest, and are recognized as an expense over the related period of service or the vesting period, whichever is longer. Under the provisions of ASC 718, members of the Board are considered employees for calculation of stock-based compensation expense.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

We estimated the fair value of the stock options granted on the date of grant using a Black-Scholes valuation model that used the weighted average assumptions noted in the following table. The risk-free interest rate assumption we use is based upon United States Treasury interest rates appropriate for the expected life of the awards. The expected life (estimated period of time that we expect employees, directors, and consultants to hold their stock options) was estimated based on historical rates for three group classifications, (i) employees, (ii) outside directors and officers, and (iii) consultants. Expected volatility was based on historical volatility of our stock price for a period equal to the stock option's expected life and calculated on a daily basis. The expected dividend rate is zero since we do not currently pay cash dividends on our common stock and do not anticipate doing so in the foreseeable future.

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2016	**2015**	**2016**	**2015**
Risk-free interest rate	1.17%	2.03%	1.53%	1.99%
Expected life (in years)	5.20	7.40	6.77	6.91
Expected volatility	77 %	84 %	74 %	82 %
Expected dividend yield	--	--	--	--

Stock-based compensation expense for the three and nine months ended September 30, 2016 and 2015 was recorded in our condensed consolidated statement of operations as follows (in thousands):

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2016	**2015**	**2016**	**2015**
Research and development expenses	$186	$235	$635	$991
General and administrative expenses	236	259	1,323	1,714
Total stock-based compensation expense	**$422**	**$494**	**$1,958**	**$2,705**

At September 30, 2016, unrecognized stock-based compensation expense related to stock options was approximately $2.9 million and is expected to be recognized over a weighted average period of approximately 2.5 years.

Note 12. Subsequent Event

On November 4, 2016, through a new wholly-owned subsidiary MNTX Royalties Sub LLC (“MNTX Royalties”), we entered into a loan agreement (the “Royalty-Backed Loan”) with a fund managed by HealthCare Royalty Partners III, L.P. (“HCRP”) pursuant to which HCRP agreed to make term loans in an aggregate principal amount of up to $100.0 million. We received $50.0 million at closing and can borrow the remaining $50.0 million, subject to mutual agreement with HCRP, up to twelve months after the closing date. Under the terms of the Royalty-Backed Loan, the lenders have no recourse to us or to any of our assets other than the right to receive royalty payments from the commercial sales of RELISTOR products owed under our agreement with Valeant. The RELISTOR royalty payments will be used to repay the principal and interest on the loan. The Royalty-Backed Loan bears interest at a per annum rate of 9.5%.

Under the terms of the loan agreement, which was filed as an exhibit to Form 8-K on November 7, 2016, payments of interest and principal, if any, under the loan will be made on the last day of each calendar quarter out of RELISTOR royalty payments received since the immediately preceding payment date. On each payment date prior to March 31, 2018, RELISTOR royalty payments received since the immediately preceding payment date will be applied solely to the payment of interest on the loan, with any royalties in excess of the interest amount retained by us. Beginning on March 31, 2018, 50 per cent of RELISTOR royalty payments received since the immediately preceding payment date in excess of accrued interest on the loan will be used to repay the principal of the loan, with the balance retained by us. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid. The loan has a maturity date of June 30, 2025. Upon the occurrence of certain triggers in the loan agreement, or if HCRP so elects on or after January 1, 2018, all of the RELISTOR royalty payments received after the immediately preceding payment date shall be applied to the payment of interest and repayment of principal until the principal of the loan is fully repaid. In the event of such an election by HCRP, we have the right to repay the loan without any prepayment penalty.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) - Continued

On October 25, 2016, we received notification of a Paragraph IV certification for certain patents for RELISTOR Tablets, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certification resulted from the filing by Actavis LLC of an ANDA challenging such patents for RELISTOR Tablets.

Progenics and Valeant continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between us and Valeant, Valeant has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to assist the reader in understanding the business of Progenics Pharmaceuticals, Inc. and its subsidiaries (the "Company," "Progenics," "we," or "us"). MD&A is provided as a supplement to, and should be read in conjunction with, our Annual Report on Form 10-K for the year ended December 31, 2015. Our results of operations discussed in MD&A are presented in conformity with accounting principles generally accepted in the U.S. ("GAAP"). We operate under a single research and development business segment. Therefore, our results of operations are discussed on a consolidated basis.

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. Statements contained in this communication that refer to our estimated or anticipated future results or other non-historical facts are forward-looking statements that reflect our current perception of existing trends and information as of the date of this communication. Forward looking statements generally will be accompanied by words such as "anticipate," "believe," "plan," "could," "should, "estimate," "expect" "forecast," "outlook," "guidance," "intend," "may," "might," "will," "possible," "potential," "predict," "project," or other similar words, phrases or expressions. Such statements are predictions only, and are subject to risks and uncertainties that could cause actual events or results to differ materially. 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 between forward-looking statements and our actual results, performance or achievement 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 which appear to be promising in early trials will not demonstrate efficacy or safety in larger-scale trials; the sales of RELISTOR® and other products by our partners and the revenue and income generated for us thereby may not meet expectations; 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 obtain sufficient capital, recruit and retain employees, enter into favorable collaborations or transactions, or other relationships or that existing or future relationships or transactions 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 to which we are subject 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, that any of our other programs will result in a commercial product, or that we will be able to successfully complete our integration of EXINI Diagnostics AB ("EXINI") and to develop and commercialize its products.

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We do not have a policy of updating or revising forward-looking statements and, except as expressly required by law, we disclaim any intent or obligation to update or revise 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

Business

We develop innovative medicines and other products for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA® and 1095), and imaging agents (1404 and PyL™) intended to enable clinicians and patients to accurately visualize and manage their disease. In April 2016, we entered into an agreement with a subsidiary of Bayer AG ("Bayer") granting Bayer exclusive worldwide rights to develop and commercialize products using our prostate specific membrane antigen ("PSMA") antibody technology in combination with Bayer's alpha-emitting radionuclides. In addition, as part of our acquisition of EXINI Diagnostics AB ("EXINI") in late 2015, we acquired the EXINI Bone BSI bone scan index product, which is approved for use in Europe, Japan, and the U.S. (though not yet available in the U.S.).

Products in Development

Our goal is to become a patient-centered oncology company, focused on the intersection of imaging and treatment. We intend to make a difference in how patients with prostate cancer, pheochromocytoma, and paraganglioma are diagnosed and treated by advancing the following product candidates through clinical development:

Product / Candidate	Description	Status
AZEDRA	Treatment of malignant and/or recurrent pheochromocytoma and paraganglioma	Completed dosing in registrational trial under Special Protocol Assessment ("SPA") with the Food and Drug Administration ("FDA"); an Expanded Access Program is planned and will be initiated by year end
1404	Technetium-99m labeled PSMA targeted SPECT/CT imaging agent for prostate cancer	Phase 3 pivotal trial in progress
1404 Index		In development

	Analytical tool for analysis and indexing of 1404 images for prostate cancer	
PyL	Fluorinated PSMA-targeted PET/CT imaging agent for prostate cancer	Phase 2/3 trial expected to commence in late fourth quarter of 2016
PyL Index	Analytical tool for analysis and indexing of PyL images for prostate cancer	In development
1095	Treatment of metastatic prostate cancer	Phase 1 trial expected to commence in late fourth quarter of 2016
EXINI Bone BSI	Analytical tool for analysis of Bone Scan Index from bone scintigraphy images	Currently sold in Europe and Japan; planning for U.S. commercialization in process

We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving proprietary research, development, clinical and commercialization programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

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Partnered Products

Our partnered commercial products and drug candidates are:

Products in Development	**Indication**	**Status**
RELISTOR-Subcutaneous injection	Treatment of opioid-induced constipation ("OIC") in advanced-illness patients receiving palliative care when laxative therapy has not been sufficient and treatment of OIC in patients with non-cancer pain	Sold in the U.S., E.U., Canada, Australia and elsewhere; licensed to Valeant
RELISTOR-Oral Tablets	Treatment of OIC in adults with chronic non-cancer pain	Approved by the FDA on July 19, 2016; U.S. commercialization commenced in third quarter of 2016; licensed to Valeant
PSMA Antibody conjugated with alpha-emitting radionuclides	Treatment of prostate and other forms of cancer	Lead optimization in process; licensed to Bayer on April 28, 2016
PRO 140	HIV treatment	Phase 3 study ongoing; licensed to CytoDyn Inc.

Under our agreement with Valeant, we received a development milestone of $40.0 million upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients in 2014, and a development milestone of $50.0 million for the July 19, 2016 U.S. marketing approval of an oral formulation of RELISTOR. We are also eligible to receive up to $200.0 million of commercialization milestone payments upon achievement of specified U.S. sales targets, including:

$10 million based on the first achievement of combined U.S. net sales in excess of $100 million in any single calendar year;
$15 million based on the first achievement of combined U.S. net sales in excess of $150 million in any single calendar year;
$20 million based on the first achievement of combined U.S. net sales in excess of $200 million in any single calendar year;
$30 million based on the first achievement of combined U.S. net sales in excess of $300 million in any single calendar year;
$50 million based on the first achievement of combined U.S. net sales in excess of $750 million in any single calendar year; and

$75 million based on the first achievement of combined U.S. net sales in excess of $1 billion in any single calendar year.

Each commercialization milestone payment is payable one time only, regardless of the number of times the condition is satisfied, and all six payments could be made within the same calendar year. We are also eligible to receive royalties from Valeant and its affiliates based on the following royalty scale: 15% on worldwide net sales up to $100 million, 17% on the next $400 million in worldwide net sales, and 19% on worldwide net sales over $500 million each calendar year, and 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Valeant receives from sublicensees outside the U.S.

Valeant has also entered into license and distribution agreements to expand its sales channels outside of the U.S. for RELISTOR. During the second quarter of 2016, we recognized collaboration revenue of $720 thousand for our share of the upfront payment Valeant received from Lupin Limited pursuant to a distribution agreement for RELISTOR in Canada.

Under the agreement with Bayer, we received an upfront payment of $4.0 million and could receive up to an additional $49.0 million in potential clinical and regulatory development milestones. We are also entitled to single digit royalties on net sales, and potential net sales milestone payments up to an aggregate total of $130.0 million. During the second quarter of 2016, we recognized collaboration revenue of $5.0 million, of which $4.0 million related to the upfront payment and $1.0 million related to the achievement of a preclinical development milestone.

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Subsequent Event

On November 4, 2016, through a new wholly-owned subsidiary MNTX Royalties Sub LLC ("MNTX Royalties"), we entered into a loan agreement (the "Royalty-Backed Loan") with a fund managed by HealthCare Royalty Partners III, L.P. ("HCRP") pursuant to which HCRP agreed to make term loans in an aggregate principal amount of up to $100.0 million. We received $50.0 million at closing and can borrow the remaining $50.0 million, subject to mutual agreement with HCRP, up to twelve months after the closing date. Under the terms of the Royalty-Backed Loan, the lenders have no recourse to us or to any of our assets other than the right to receive royalty payments from the commercial sales of RELISTOR products owed under our agreement with Valeant. The RELISTOR royalty payments will be used to repay the principal and interest on the loan. The Royalty-Backed Loan bears interest at a per annum rate of 9.5%.

Under the terms of the loan agreement, which was filed as an exhibit to Form 8-K on November 7, 2016, payments of interest and principal, if any, under the loan will be made on the last day of each calendar quarter out of RELISTOR royalty payments received since the immediately preceding payment date. On each payment date prior to March 31, 2018, RELISTOR royalty payments received since the immediately preceding payment date will be applied solely to the payment of interest on the loan, with any royalties in excess of the interest amount retained by us. Beginning on March 31, 2018, 50 per cent of RELISTOR royalty payments received since the immediately preceding payment date in excess of accrued interest on the loan will be used to repay the principal of the loan, with the balance retained by us. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid. The loan has a maturity date of June 30, 2025. Upon the occurrence of certain triggers in the loan agreement, or if HCRP so elects on or after January 1, 2018, all of the RELISTOR royalty payments received after the immediately preceding payment date shall be applied to the payment of interest and repayment of principal until the principal of the loan is fully repaid. In the event of such an election by HCRP, we have the right to repay the loan without any prepayment penalty.

Results of Operations

The following table is an overview of our results of operations (in thousands, except percentages):

	Three Months Ended September 30,				**Nine Months Ended September 30,**			
	2016	**2015**	**Change**		**2016**	**2015**	**Change**	
Total revenue	$53,850	$1,396	3757	%	$64,777	$3,581	1709	%
Operating expenses	$17,647	$11,420	(55	%)	$47,001	$35,579	(32	%)
Operating income (loss)	$36,203	$(10,024)	461	%	$17,776	$(31,998)	156	%

Net income (loss)	$36,282	$(10,014)	462	%	$17,952	$(31,965)	156	%
Net income (loss) attributable to Progenics	$36,303	$(10,014)	463	%	$18,010	$(31,965)	156	%

Revenue

Our sources of revenue include license and other agreements with Valeant and other collaborators and, to a small extent, sale of research reagents. The following table is a summary of our worldwide revenue (in thousands, except percentages):

	Three Months Ended September 30,				**Nine Months Ended September 30,**			
Source	**2016**	**2015**	**Change**		**2016**	**2015**	**Change**	
Royalty income	$3,319	$1,208	175	%	$7,888	$3,155	150	%
Collaboration revenue	50,523	183	27508	%	56,839	393	14363	%
Other revenue	8	5	60	%	50	33	52	%
Total revenue	**$53,850**	**$1,396**	**3757**	**%**	**$64,777**	**$3,581**	**1709**	**%**

Total revenue increased by $52.5 million and $61.2 million, or 3,757% and 1,709%, to $53.9 million and $64.8 million during the three and nine months ended September 30, 2016, respectively, compared to the three and nine months ended September 30, 2015. The increases were primarily attributable to higher collaboration revenue under the Valeant license agreement, upfront and milestone revenue under the Bayer license agreement, and higher RELISTOR royalty income. The 2016 periods benefited from the receipt of a development milestone of $50.0 million for the U.S. marketing approval of an oral formulation of RELISTOR.

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We recognized royalty income primarily based on the below net sales of RELISTOR as reported to us by Valeant (in thousands).

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
U.S.	$21,500	$7,400	191 %	$51,600	$18,400	180 %
Outside U.S.	600	600	0 %	3,000	2,400	25 %
Worldwide net sales of RELISTOR	**$22,100**	**$8,000**	**176 %**	**$54,600**	**$20,800**	**163 %**

Valeant reported the above net sales, resulting in royalty income of $3.3 million and $7.9 million for the three and nine months ended September 30, 2016, respectively, and $1.2 million and $3.2 million for the three and nine months ended September 30, 2015, respectively. Valeant's reported net sales for the three and nine months ended September 30, 2016 include a non-recurring favorable sales return adjustment.

Operating Expenses

The following table is a summary of our operating expenses (in thousands, except percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,		
Operating Expenses	**2016**	**2015**	**Change**	**2016**	**2015**	**Change**
Research and development	$9,827	$7,048	(39%)	$26,964	$20,255	(33%)
General and administrative	7,220	4,572	(58%)	18,637	14,424	(29%)
Change in contingent consideration liability	600	(200)	(400%)	1,400	900	(56%)
Total operating expenses	**$17,647**	**$11,420**	**(55%)**	**$47,001**	**$35,579**	**(32%)**

Research and Development ("R&D")

R&D expenses increased by $2.8 million and $6.7 million, or 39% and 33%, during the three and nine months ended September 30, 2016, respectively, compared to the three and nine months ended September 30, 2015. The increases during the three- and nine-month periods were primarily attributable to higher clinical trial and contract manufacturing expenses for 1404, AZEDRA, PyL and 1095.

General and Administrative ("G&A")

G&A expenses increased by $2.6 million and $4.2 million, or 58% and 29%, during the three and nine months ended September 30, 2016, respectively, compared to the three and nine months ended September 30, 2015. The increase in the three-month period was primarily attributable to an accrual for front pay compensation related to litigation with a former employee, and higher consulting and market research expenses. The increase during the nine-month period was primarily attributable to higher depreciation expense as a result of a reduction in the remaining useful lives of our leasehold improvements at our Tarrytown, NY former location, and higher compensation, consulting, and market research expenses.

Other Income

The following table is a summary of our other income (in thousands, except percentages):

	Three Months Ended September 30,				**Nine Months Ended September 30,**			
Other Income	**2016**	**2015**	**Change**		**2016**	**2015**	**Change**	
Interest income	$ 79	$ 10	690	%	$ 176	$ 33	433	%
Other income	**$ 79**	**$ 10**	**690**	**%**	**$ 176**	**$ 33**	**433**	**%**

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Other income increased by $69 thousand and $143 thousand during the three and nine months ended September 30, 2016, respectively, compared to the three and nine months ended September 30, 2015. The increases during the three- and nine-month periods were primarily attributable to higher average cash balances in 2016 than in 2015 and higher average interest rates earned by our money market funds.

Liquidity and Capital Resources

The following table is a summary of selected financial data (in thousands):

	September 30, 2016	**December 31, 2015**
Cash and cash equivalents	$ 98,894	$ 74,103
Accounts receivable, net	$ 3,942	$ 3,543
Total assets	$ 156,937	$ 131,251
Working capital	$ 92,790	$ 73,556

We have to-date funded operations principally through payments received from private placements of equity securities, public offerings of our common stock, up-front payments, development milestones, and royalties from license agreements, and proceeds from the exercise of stock options.

At September 30, 2016, we held $98.9 million in cash and cash equivalents, an increase of $24.8 million from $74.1 million at December 31, 2015. We believe our existing balances of cash and cash equivalents, together with the proceeds from the Royalty-Backed Loan, will be sufficient to satisfy our working capital needs, capital asset purchases, outstanding commitments, and other liquidity requirements associated with our existing operations over the next twelve (12) months.

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.

During the first quarter of 2014, we established a $150.0 million shelf registration statement, which we used for our February 2014 underwritten public offering of 8.75 million shares of common stock at a public offering price of $4.60 per share, resulting in net proceeds of approximately $37.5 million. We may utilize this shelf registration for the

issuance of up to approximately $110.0 million of additional common stock and other securities, including up to $50.0 million of our common stock under an agreement with an investment bank providing for at-the-market sales through the bank. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. There can be no assurance, however, that any contemplated additional financing will be available on terms acceptable to us, if at all.

Cash Flows

The following table is a summary of our cash flow activities (in thousands):

	Nine Months Ended September 30,	
	2016	**2015**
Net cash provided by (used in) operating activities	$27,257	$(29,651)
Net cash used in investing activities	$(2,920)	$(228)
Net cash provided by financing activities	$510	$1,015

Operating Activities

Net cash provided by operating activities during the nine months ended September 30, 2016 was primarily attributable to the $50.0 million milestone payment from Valeant for the approval of RELISTOR Tablets, partially offset by operating expenses, net of non-cash items.

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Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2016 was primarily related to capital expenditures, partially offset by proceeds from the sale of fixed assets.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2016 was related to proceeds from the exercise of stock options.

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 U.S. Our significant accounting policies are disclosed in *Note 2. Summary of Significant Accounting Policies* to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015. 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. We evaluate these estimates on an ongoing basis. We base these estimates on historical experience and on various other assumptions that we believe reasonable under the circumstances. The results of these evaluations 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, they 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 September 30, 2016, which are disclosed in Management's Discussion and Analysis of Financial Condition and

Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Recent Accounting Developments

Refer to our discussion of recently adopted accounting pronouncements and other recent accounting pronouncements in *Note 2. New Accounting Pronouncements* to the accompanying unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 $97.3 million at September 30, 2016. As a result, we do not believe that these investment balances have a material exposure to interest-rate risk.

The majority of our business is conducted in U.S. dollars. However, we do conduct certain transactions in other currencies, including Euros, British Pounds, Swiss Francs, and Swedish Krona. Historically, fluctuations in foreign currency exchange rates have not materially affected our consolidated results of operations and during the three and nine months ended September 30, 2016 and 2015, our consolidated results of operations were not materially affected by fluctuations in foreign currency exchange rates.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports, 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 Chief Financial Officer ("CFO"), 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.

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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 CFO, 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 CFO 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 have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Except for the former employee litigation described below, there have been no other material changes from the information discussed in Part I, Item 3. Legal Proceedings of our Annual Report on Form 10-K for the year ended December 31, 2015. We are or may be from time to time involved in various other disputes, governmental, and/or regulatory inspections, inquiries, investigations, and proceedings that could result in litigation, and other litigation matters that arise from time to time. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect us, our results of operations, financial condition, and cash flows. Refer to our discussion in *Note 9. Commitments and Contingencies* to the accompanying unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We are 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 we had violated the anti-retaliation provisions of the Federal Sarbanes-Oxley law by terminating the former employee. The former employee sought reinstatement of his employment, compensatory damages, and certain costs and fees associated with the litigation. In July 2013, the Federal District Court hearing the case issued an order denying our motion for summary judgment dismissing the former employee's complaint. The case went to trial in July 2015 and, on July 31, 2015, the jury awarded the former employee approximately $1.7 million in compensatory damages (held in escrow by the District Court and recorded as restricted cash in other current assets on our condensed consolidated balance sheet) primarily consisting of salary the former employee would have received during the period from his termination to the date of the verdict. On August 30, 2016, the judge issued an opinion and awarded the former employee approximately $3.3 million for front pay compensation and pre-judgment interest. As a result, we recorded an additional accrual of $2.5 million in the three months ended September 30, 2016 related to this matter. At September 30, 2016, we had an aggregate amount of approximately $5.0 million accrued for this loss contingency deemed probable and estimable, which is included in

accrued expenses on our condensed consolidated balance sheet. We have filed for an appeal.

Item 1A. Risk Factors

You should carefully consider the risks and uncertainties we discussed below before deciding to invest in, or retain, shares of our common stock. These are not the only risks and uncertainties that we face. Additional risks and uncertainties that we do not currently know about or that we currently believe are immaterial, or that we have not predicted, may also harm our business operations or adversely affect us. If any of these risks or uncertainties actually occurs, our business, financial condition, operating results, or liquidity could be materially harmed.

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Product Development-related Risks

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.

The future of our business and operations depends on the success of our RELISTOR collaborations and our oncology research and development and commercialization programs.

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 involve novel approaches to human therapeutics. Our principal product candidates are in 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 and commercialization 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, regulatory, technological and policy developments and trends. Moreover, assessing process capability takes time after the launch of a pharmaceutical product as process experience grows with manufacturing experience and products are periodically evaluated for improvements or specification revisions. The oncology space in which we operate presents numerous significant risks and uncertainties that may be expected to increase to the extent it becomes more competitive or less favored in the commercial healthcare marketplace.

The long-term success of our acquisitions of Molecular Insight and EXINI will be subject to all of the risks and uncertainties described in these risk factors. In addition, the estimated fair values of Molecular Insight assets and liabilities reflected in our financial statements do not, given their uniqueness and attendant uncertainties, 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 our product candidates, technologies or programs could have an adverse impact on our business, and on the price of our stock.

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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. 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.

We, our collaborators or regulators may also amend, suspend or terminate clinical trials if we or they believe that the participating patients 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 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 our product candidates may be significantly delayed or terminated altogether.

If the results of any of our future product candidate trials are not satisfactory or we or our collaborators encounter problems enrolling patients, 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 our product candidates 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 trial of PSMA ADC, Phase 3 trial of 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 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.

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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.

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 if we or our collaboration partners overprice our products relative to those of our competitors, or fail to obtain acceptable prices or an adequate level of reimbursement for products from third-party payers or government agencies.

The commercial success of our products will depend upon their acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Market acceptance of approved products, such as RELISTOR for patients with advanced illnesses and for those with chronic, non-cancer pain, is affected by a wide range of factors, including the timing of regulatory approvals, product launches and the presence of generic, over-the-counter or other competitors; the pricing of the product and relative prices of competing products; product development efforts for new indications; the availability of reimbursement for the product; our ability to obtain 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. 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 payers 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 payers 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 most

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.

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RELISTOR-related Risks

We are dependent on Valeant to develop and commercialize RELISTOR, exposing us to significant risks.

We rely on Valeant to complete development and obtain regulatory approvals for RELISTOR worldwide. At present, our revenue is almost exclusively derived from royalty and milestone payments from our RELISTOR collaboration with Valeant, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue. 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. For example, Valeant has a variety of marketed products and 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 have commercial and financial interests that are not fully aligned with ours in a given territory or territories - which may make it more difficult for us to fully realize the value of RELISTOR, particularly in markets outside the U.S. 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.

Under our agreements with Valeant relating to RELISTOR, we rely on Valeant to, among other things, effectively commercialize the product and manage pricing, sales and marketing practices and inventory levels in the distribution channel. Assessing and reporting on these and other activities and metrics in connection with RELISTOR has become increasingly difficult as a result of financial reporting and internal control issues that have surfaced both at Valeant and its predecessor as our RELISTOR licensee, Salix. Our already limited visibility into the internal operations of Valeant and reliance on Valeant to accurately report information concerning the commercialization of RELISTOR has been further obscured by certain recent events at Valeant. On February 22, 2016 Valeant announced that it believed that approximately $58 million of net revenues previously recognized in the second half of 2014 should not have been recognized during that period, and that it expected to delay the filing of its Annual Report on Form 10-K. Both Valeant’s Form 10-K for 2015 and its Form 10-Q for the first quarter of 2016 were filed late, resulting in Valeant receiving notices of default from certain of its noteholders, in each instance. We remain exposed to Valeant’s credit risk and the possibility of default under the RELISTOR License Agreement in the event that Valeant were to terminate the agreement at its discretion or to become insolvent or bankrupt. Valeant may attempt to dispose of Salix and/or the RELISTOR License Agreement to an acquirer, which — depending on the identity of such acquirer — could

expose us to greater counterparty risk of a breach under such agreement. Valeant further announced that it continued to work with its independent advisors in its ongoing assessment of the impact on financial reporting and internal controls of the accounting issues it had discovered. Valeant commenced remediation efforts with respect to financial reporting and internal controls in the second quarter of 2016, and restated certain previously issued financial statements in its report on Form 10-Q for the same quarter. However, there is no assurance as to the adequacy of such efforts in averting future losses incurred in connection with any failures of Valeant's internal controls. Furthermore, prior to its acquisition by Valeant, Salix disclosed in January of 2015, in connection with an internal review of issues related to its management's prior characterizations of wholesaler inventory levels, that Salix's previously issued audited consolidated financial statements for the year ended December 31, 2013 and the first nine months of 2014, and the disclosures and related communications for each of those periods, required correction of certain errors and should no longer be relied upon. Valeant continues its efforts to assess and manage the potential ramifications relating to Salix's restatement of its historical financial results and Valeant's internal control over financial reporting.

The RELISTOR commercialization 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.

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Although the FDA approved RELISTOR Tablets for the treatment of opioid-induced constipation in adults with chronic non-cancer pain and Valeant subsequently announced the U.S. commercial launch of the product on September 6, 2016, there can be no assurances that we and our partners will be able to successfully obtain approval to market oral RELISTOR outside the U.S. or for any other indications. In addition, our and our partners' ability to optimally commercialize either oral or subcutaneous RELISTOR in a given jurisdiction may be impacted by applicable labeling and other regulatory requirements. 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 and/or commercialization programs for oral RELISTOR and our other products and product candidates 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.

Certain RELISTOR-related patents are subject to generic challenge.

In October 2015 Progenics received notifications of Paragraph IV certifications with respect to certain patents for RELISTOR subcutaneous injection, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certifications accompanied the filing by Actavis Inc. and Mylan Pharmaceuticals, Inc. of Abbreviated New Drug Applications (ANDAs) challenging such patents for RELISTOR subcutaneous injection.

Progenics and its licensee for RELISTOR, Valeant, have timely filed suit and commenced litigation against Actavis and Mylan. FDA approval of the ANDA has been automatically stayed until the earlier of (i) 30 months from receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

In October 2016 Progenics received a notification of a Paragraph IV certification with respect to certain patents for RELISTOR Tablets, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certification accompanied the filing by Actavis LLC. of an ANDA challenging such patents for RELISTOR Tablets. Progenics and its licensee for RELISTOR, Valeant, are assessing the notification and intend to vigorously enforce RELISTOR intellectual property rights.

In addition to the above described ANDA notifications, in October 2015 Progenics also received notices of opposition to three European patents (EP 1615646, EP 2368554 and EP 2368553) relating to methylnaltrexone. The oppositions

were filed separately by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH.

Although Progenics and Valeant are cooperating to defend against both the ANDA challenges and the European oppositions, and intend to vigorously enforce RELISTOR intellectual property rights, such litigation is inherently subject to significant risks and uncertainties, and there can be no assurance that the outcome of these litigations will be favorable to Progenics or Valeant. An unfavorable outcome in these cases could result in the rapid genericization of RELISTOR products, or could result in the shortening of available patent life. Any such outcome could have a material impact on our financial performance and stock price.

Pursuant to the RELISTOR license agreement between Progenics and Valeant, Valeant has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement. At the same time, supporting the conduct of the litigations in the U.S. and in Europe will continue to require significant management focus and internal resources of Progenics.

Operational and Regulatory Risks

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.

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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 REMS. For example, while subcutaneous RELISTOR is approved for OIC both in patients with advanced illness and for those with chronic, non-cancer pain, the oral formulation of and/or indication for RELISTOR is restricted to adult patients with chronic non-cancer pain. Approvals for product candidates other than RELISTOR, if approved at all, may also be 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. Valeant's subsidiary Salix 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. Salix subsequently has become the subject of an SEC investigation and, beginning on November 7, 2004, the target of three putative class action lawsuits filed by shareholders of Salix. Valeant has indicated that as of the filing of its report on Form 10-Q for the second quarter of 2016, it cannot predict the outcome or the duration of the SEC investigation or any other legal proceedings or any enforcement actions or other remedies that may be imposed on Salix or Valeant arising out of the SEC investigation. Accordingly, no assurance can be given as to Valeant's financial condition or results of operations, or ability to meet its royalty or milestone obligations to Progenics.

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 (including different or aggravated effects such as SAEs encountered in our 1095 and PSMA ADC programs) 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 (including those arising from SAEs heretofore or hereafter encountered in our PSMA ADC program) 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.

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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.

Our and/or our collaborators' relationships with customers and third-party payers are or may become 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 payers 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 payers and customers will or already do require us and them to comply with 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.

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 result in the supply of insufficient 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 may 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 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. We continue to be dependent on a limited number of highly specialized manufacturing and development partners, including single source manufacturers for certain of our product candidates. If we were to lose one or more of these key relationships, it could materially adversely affect our business. Establishing new manufacturing relationships, or creating our own manufacturing capability, would require significant time, capital and management effort, and the transfer of product-related technology and know-how from one manufacturer to another is an inherently complex and uncertain process.

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Failure of any manufacturer of RELISTOR or our various 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 supply us with our product or product candidates. 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 operations 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.

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.

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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.

The original patents surrounding the AZEDRA program were licensed by Molecular Insight from the University of Western Ontario (“UWO”). The patent family directed to processes for making polymer precursors, as well as processes for making the final product expire in 2018 in the U.S. and Canada. Other licensed patent families from UWO relate to alternative approaches for preparing AZEDRA, which if implemented would expire in 2024, worldwide. Progenics has pending applications worldwide directed to manufacturing improvements and the resulting compositions which, if issued, would expire in 2035.

Owned and in-licensed properties relating to the 1404 product candidate have expiration ranges of 2020 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 and 2030 in the U.S.; 2029 in the rest of the world. Patent applications directed to methods of use are pending worldwide, which if issued would expire in 2034.

Patent protection for the PyL compound, radiolabeled form of the compound, as well as methods of use expire in 2030 in the U.S. Corresponding family members are pending or issued worldwide, all with expirations of 2029.

Company-owned properties relating to MIP-1095 have expiration ranges of 2027 to 2031 in the U.S. We view as most significant the composition-of-matter patent on this compound, as well as radiolabeled forms, which expires in 2027 in the U.S., as well as Europe. Additional U.S. patents are directed to stable compositions and radiolabeling processes, and expire in 2030 and 2031, respectively.

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 a pending U.S. application which would expire in 2026, if issued. An allowed U.S. application directed to methods of use will expire in 2029. Corresponding foreign counterparts to the U.S. composition-of-matter patents will expire 2022 and 2026, along with a method of use patent which expires in 2029. We view all of these patents as significant.

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. Valeant has listed in the FDA Orange Book six U.S. patents relating to subcutaneous RELISTOR, which have expiration dates ranging from 2017 to 2030, and two patents (expiring in 2024 and 2027) with Health Canada. Six Orange Book listed U.S. patents provide protection for the oral RELISTOR methylnaltrexone product, the last of which expire in 2031.

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 from SGI. We could 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.

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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 certain 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, the patentability of these pending patent applications and the applicability of any of them to our products and 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 product often require choosing between alternative development and optimization routes at various stages in the development process. Preferred routes may 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.

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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.

If we are unable to negotiate suitable 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.

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 would be required to build the commercial infrastructure required to market, sell and support it without a third-party partner. 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.

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We are involved in various legal proceedings that are uncertain, costly and time-consuming and could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

From time to time we are involved in legal proceedings and disputes and may be involved in litigation in the future. These proceedings are complex and extended and occupy the resources of our management and employees. These proceedings are also costly to prosecute and defend and may involve substantial awards or damages payable by us if not found in our favor. We may also be required to pay substantial amounts or grant certain rights on unfavorable terms in order to settle such proceedings. Defending against or settling such claims and any unfavorable legal decisions, settlements or orders could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline. For more information regarding legal proceedings, see notes 9 and 12 in the notes to the condensed consolidated financial statements in Item 1 of this Form 10-Q.

In particular, the pharmaceutical and medical device industries historically have generated substantial litigation concerning the manufacture, use and sale of products and we expect this litigation activity to continue. As a result, we expect that patents related to our products will be routinely challenged, and our patents may not be upheld. In order to protect or enforce patent rights, we may initiate litigation against third parties. If we are not successful in defending an attack on our patents and maintaining exclusive rights to market one or more of our products still under patent protection, we could lose a significant portion of sales in a very short period. We may also become subject to infringement claims by third parties and may have to defend against charges that we violated patents or the proprietary rights of third parties. If we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell products, or could be required to pay monetary damages or royalties to license proprietary rights from third parties.

In addition, in the U.S., it has become increasingly common for patent infringement actions to prompt claims that antitrust laws have been violated during the prosecution of the patent or during litigation involving the defense of that patent. Such claims by direct and indirect purchasers and other payers are typically filed as class actions. The relief sought may include treble damages and restitution claims. Similarly, antitrust claims may be brought by government entities or private parties following settlement of patent litigation, alleging that such settlements are anti-competitive and in violation of antitrust laws. In the U.S. and Europe, regulatory authorities have continued to challenge as anti-competitive so-called “reverse payment” settlements between branded and generic drug manufacturers. We may also be subject to other antitrust litigation involving competition claims unrelated to patent infringement and prosecution. A successful antitrust claim by a private party or government entity against us could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

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 amounts and pursuant to terms and conditions customary for our industry, scale and the nature of our activities (subject to a deductible and an 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.

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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 payers 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 payers 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 payers 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 payers 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.

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

Risks associated with our operations outside of the United States could adversely affect our business.

Although we currently conduct nearly all of our business in the United States, we are developing internationally and therefore have an increased exposure to foreign legal requirements, economic and political conditions and fluctuations in foreign currency exchange rates. We expect that we will continue to seek global opportunities for our products and to develop our business outside the U.S. in the future. Such opportunities and development will inherently subject us to a number of risks and uncertainties, including:

- changes in international regulatory and compliance requirements that could restrict our ability to develop, market and sell our products;
- political and economic instability;
- the impact of the vote by the United Kingdom decided by referendum to leave the European Union (commonly referred to as "Brexit");
- diminished protection of intellectual property in some countries outside of the U.S.;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing international operations;
- differing labor regulations and business practices;
- potentially negative consequences from changes in or interpretations of tax laws;
- changes in international medical reimbursement policies and programs;
- financial risks such as longer payment cycles, difficulty collecting accounts receivable and exposure to fluctuations in foreign currency exchange rates; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' and service providers' activities that may fall within the purview of the FCPA or similar foreign laws such

as the U.K. Bribery Act.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. These or other similar risks could adversely affect our revenue and profitability. As we develop internationally, our exposure to these factors will increase.

Competitive Risks

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

We are aware of a number of products and product candidates described in this Annual Report under *Business – Competition* which compete or may potentially compete with RELISTOR. Any of these approved products or product candidates, or others which may be developed in the future, may achieve a significant competitive advantage relative to RELISTOR, and, in any event, the existing or future marketing and sales capabilities of these competitors may impair Valeant's and/or other collaborators' ability to compete effectively in the market.

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We are also aware of competitors, including those described 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.

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 this Annual Report under *Business – Competition*, 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 those described 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.

Financial Risks

We have significant debt - and failure by us or our royalty subsidiary to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate.

In November 2016, our subsidiary, MNTX Royalties, entered into a Royalty-Backed Loan with HCRP pursuant to which MNTX Royalties borrowed $50.0 million and have the ability, subject to mutual agreement with HCRP, to borrow an additional $50.0 million up to twelve months after the initial closing date of the loan. The loan will be repaid from the royalty payments from the commercial sales of RELISTOR products owed under our agreement with Valeant.

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The obligations of MNTX Royalties under the loan agreement to repay the Royalty-Backed Loan may be accelerated upon the occurrence of certain events of default, including but not limited to, if:

- MNTX Royalties fails to pay any principal or interest (except as permitted) within three Business days of when such payment is due and payable or otherwise made in accordance with the terms of the Royalty-Backed Loan;
- MNTX Royalties fails to pay when due any indebtedness of $15 thousand or more;
- any representation or warranty made by MNTX Royalties in the loan agreement or any other transaction document proves to be incorrect or misleading in any material respect when made, and such failure is uncured on or before the 30th day following notice thereof;
- MNTX Royalties fails to perform or observe any covenant or agreement contained in the loan agreement or any other transaction document;
- any uninsured judgment, decree, or order in an amount in excess of $25 thousand is rendered against MNTX Royalties and enforcement proceedings have commenced upon such judgment, decree, or order or such judgment, decree, or order has not been stayed or bonded pending appeal, vacated, or discharged, within 30 days from entry;
- any of a set of defined insolvency events occurs;
- we default under the agreement pursuant to which we contributed the royalty and related rights under the RELISTOR license to MNTX Royalties, and such default is continuing;
- any of the loan transaction documents cease to be in full force and effect or valid and enforceable;
- MNTX Royalties fails to perform or observe any covenant or agreement contained in any material contract and such failure is not cured or waived within any applicable grace period;
- the agreement with Valeant is terminated or cancelled and is not replaced within 270 days after such termination or cancellation; and
- any security interest purported to be created by the loan agreement or the related security agreement ceases to be in full force and effect, or any rights, powers, and privileges purported to be created and granted under the loan agreement or such security agreement ceases to be in full force and effect.

In connection with the Royalty-Backed Loan, MNTX Royalties granted a first priority lien and security interest (subject only to certain defined permitted liens) in all of its assets and all real, intangible and personal property, including all of its right, title, and interest in and to the royalty payments under our agreement with Valeant. Under the terms of the loan agreement, HCRP has no recourse for non-payment of the Royalty-Backed Loan to Progenics Pharmaceuticals, Inc., or to any of our assets other than the RELISTOR royalty rights held by MNTX Royalties. However, Progenics Pharmaceuticals, Inc. does have certain obligations that run to the benefit of HCRP with respect to the representations, warranties and covenants it makes under the agreement pursuant to which we contributed the royalty and related rights under the RELISTOR License to MNTX Royalties. A breach of these obligations could lead to recourse against Progenics Pharmaceuticals, Inc. with respect to any losses suffered by HCRP as a result of such breach.

Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations, and limit our ability to react to changes in the economy or our industry.

As of November 4, 2016, our outstanding debt amounted to $50 million, which could increase to $100 million upon MNTX and HRCP's mutual agreement, over the ensuing year. These levels could have adverse consequences for us, including:

- heightening our vulnerability to downturns in our business or our industry or the general economy and restricting us from making improvements or acquisitions, or exploring business opportunities; and
- limiting our ability to adjust to changing market conditions and placing us at a competitive disadvantage compared to our competitors who have greater capital resources.

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Developing product candidates requires us to obtain additional financing from time to time. Our access to capital funding is uncertain.

We incur significant costs to develop our product candidates. We do not have committed external sources of funding for these projects. We fund our operations to a significant extent from capital-raising. We may do so via equity securities issuances in public offerings, such as our first quarter 2014 $37.5 million underwritten public offering of 8.75 million shares of common stock, through our three-year facility with an investment bank pursuant to which we may sell from time to time up to $50 million of our stock in at-the-market transactions, or through further debt financing. We may also fund operations through collaboration, license, further royalty financings, private placement or other agreements with one or more pharmaceutical or other companies, or the receipt of milestone and other payments for out-licensed products. To the extent we raise additional capital by issuing equity securities, existing stockholders could experience substantial dilution, and if we issue securities other than common stock, new investors could have rights superior to existing stockholders. Any further debt financing that we may obtain may involve operating covenants that restrict our business and significant repayment obligations. To the extent we raise additional funds through new collaboration and licensing arrangements, we may be required to relinquish some rights to technologies or product candidates, or grant licenses on terms that are not favorable to us.

We cannot predict with certainty when we will need additional funds, how much we will need, the form a financing may take or whether additional funds will be available at all. The variability of conditions in global financial and credit markets may exacerbate the difficulty of timing capital raising or other financing, as a result of which we may seek to consummate such transactions substantially in advance of immediate need. Our need for future funding will depend on numerous factors, including the advancement of existing product development projects and the availability of new projects; the achievement of events, most of which are out of our control and depend entirely on the efforts of others, triggering milestone payments to us; the progress and success of clinical trials and pre-clinical activities (including studies and manufacturing) involving product candidates, whether conducted by collaborators or us; the progress of research programs carried out by us; changes in the breadth of our research and development programs; the progress of research and development efforts of collaborators; our ability to acquire or license necessary, useful or otherwise attractive technologies; competing technological and market developments; the costs and timing of obtaining, enforcing and defending patent and other intellectual property rights; the costs and timing of regulatory filings and approvals; our ability to manage Progenics' growth or contraction; and 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 or commercialization programs, cause us 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 and may adversely affect our ability to operate as a going concern. We may not be able at a given 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.

We have a history of operating losses.

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 2015 and 2013 and while we reported operating income for 2014 and the third quarter of 2016, as a result of milestone payments from Valeant, 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. 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 and for those with chronic, non-cancer pain and RELISTOR Tablets for adult patients with chronic, non-cancer pain. Our operations may not be profitable even if any of our other product candidates under development are commercialized.

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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 $7.09 and a low of $3.61 during the nine months ended September 30, 2016, and between a high of $11.15 and a low of $4.86 in 2015. 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; 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; general market conditions; and the reporting of or commentary on such matters by the press and others. 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 in public offerings, private placements and/or through our January 2014 Sales Agreement with an investment bank, pursuant to which we may sell from time to time up to $50 million of our stock, and to issue options to purchase common stock for compensation purposes. We may issue preferred stock, restricted stock units or securities convertible into or exercisable or exchangeable for our common stock. All such issuances would dilute existing investors and could lower the price of our common stock. Sales of substantial numbers of outstanding shares of common stock, such as sales by former Molecular Insight 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, which we have done in follow-on primary offerings in late 2012, mid-2013 and February 2014. We have a shelf registration statement which may be used to issue up to approximately an additional $110 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 adversely affect the market price of our common stock.

Other Risks

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

At September 30, 2016, our directors and executive officers together beneficially owned or controlled approximately 6 percent of our outstanding common shares, including shares currently issuable upon option exercises, and our five largest other stockholders approximately 52.7 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.

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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 vesting 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
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 Patrick Fabbio, Senior Vice President and Chief Financial Officer (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 Chief Financial 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 Files:
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

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SIGNATURES

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

PROGENICS PHARMACEUTICALS, INC.

Date: November 7, 2016

By: **/s/ Patrick Fabbio**
Patrick Fabbio

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)