

PROGENICS PHARMACEUTICALS INC

Form 10-Q

November 08, 2018

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**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, 2018**

**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**

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**PROGENICS PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware**

**(State or other jurisdiction of incorporation or organization)**

**13-3379479**

**(I.R.S. Employer Identification Number)**

**One World Trade Center, 47<sup>th</sup> Floor**

**New York, NY 10007**

**(Address of principal executive offices, including zip code)**

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

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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, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth 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
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 5, 2018, a total of 84,542,514 shares of common stock, par value \$0.0013 per share, were outstanding.

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Table of Contents**PART I — FINANCIAL INFORMATION****Item 1. Financial Statements****PROGENICS PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except per share data)**

	<b>September 30, 2018 (unaudited)</b>	<b>December 31, 2017 (audited)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 148,851	\$ 90,642
Accounts receivable, net	5,821	3,972
Other current assets	2,237	2,256
Total current assets	156,909	96,870
Property and equipment, net	3,977	4,122
Intangible assets, net	6,893	30,369
Goodwill	13,074	13,074
Restricted cash	1,529	1,522
<b>Total assets</b>	<b>\$ 182,382</b>	<b>\$ 145,957</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 629	\$ 3,359
Accrued expenses	7,650	9,555
Current portion of debt, net	8,216	2,445
Total current liabilities	16,495	15,359
Long-term debt, net	38,332	47,242
Contingent consideration liability	10,900	16,800
Deferred tax liability	26	1,575
Other liabilities	1,746	1,528
<b>Total liabilities</b>	<b>67,499</b>	<b>82,504</b>

Commitments and Contingencies

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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 - 84,742 shares in 2018 and 71,645 shares in 2017	110	93
Additional paid-in capital	712,111	609,829
Treasury stock at cost, 200 shares of common stock	(2,741 )	(2,741 )
Subscription receivable	-	(2,109 )
Accumulated other comprehensive loss	(93 )	(33 )
Accumulated deficit	(594,504 )	(541,586 )
<b>Total stockholders' equity</b>	<b>114,883</b>	<b>63,453</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 182,382</b>	<b>\$ 145,957</b>

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

Table of Contents**PROGENICS PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share data)****(Unaudited)**

	<b>Three Months Ended September 30, 2018      2017</b>		<b>Nine Months Ended September 30, 2018      2017</b>	
Revenue:				
Royalty income	\$5,169	\$2,562	\$11,757	\$7,282
Other revenue	148	135	627	527
Total revenue	5,317	2,697	12,384	7,809
Operating expenses:				
Research and development	8,090	10,344	25,547	31,641
Selling, general and administrative	7,075	5,958	21,341	17,986
Intangible impairment charge	23,200	-	23,200	-
Change in contingent consideration liability	(8,000 )	700	(5,900 )	3,300
Total operating expenses	30,365	17,002	64,188	52,927
Operating loss	(25,048)	(14,305)	(51,804)	(45,118)
Other (expense) income:				
Interest (expense) income, net	(762 )	(1,047 )	(2,698 )	(3,230 )
Total other (expense) income	(762 )	(1,047 )	(2,698 )	(3,230 )
Loss before income tax benefit	(25,810)	(15,352)	(54,502)	(48,348)
Income tax benefit	1,453	-	1,549	-
<b>Net loss</b>	<b>\$(24,357)</b>	<b>\$(15,352)</b>	<b>\$(52,953)</b>	<b>\$(48,348)</b>
<b>Net loss per share - basic and diluted</b>	<b>\$(0.30 )</b>	<b>\$(0.22 )</b>	<b>\$(0.70 )</b>	<b>\$(0.69 )</b>
<b>Weighted-average shares - basic and diluted</b>	<b>80,325</b>	<b>70,270</b>	<b>75,648</b>	<b>70,233</b>

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 LOSS**

(In thousands)

(Unaudited)

	<b>Three Months Ended September 30, 2018      2017</b>		<b>Nine Months Ended September 30, 2018      2017</b>	
Net loss	\$(24,357)	\$(15,352)	\$(52,953)	\$(48,348)
Other comprehensive loss:				
Foreign currency translation adjustments	(4      )	20	(60      )	51
<b>Comprehensive loss</b>	<b>\$(24,361)</b>	<b>\$(15,332)</b>	<b>\$(53,013)</b>	<b>\$(48,297)</b>

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



Table of Contents**PROGENICS PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**

(In thousands)

(Unaudited)

	<b>Common Stock</b>		<b>Common Stock</b>		<b>Additional</b>		<b>Accumulated</b>		<b>Treasury Stock</b>		<b>Total Stockholders' Equity</b>
	<b>Number of Shares</b>	<b>Par Value</b>	<b>Number of Shares</b>	<b>Par Value</b>	<b>Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Other Comprehensive Loss</b>	<b>Subscription Receivable</b>	<b>Number of Shares</b>	<b>Cost</b>	
<b>Balance at December 31, 2017</b>	<b>71,325</b>	<b>\$93</b>	<b>320</b>	<b>\$ -</b>	<b>\$ 609,829</b>	<b>\$(541,586 )</b>	<b>\$ (33 )</b>	<b>\$(2,109 )</b>	<b>(200)</b>	<b>\$(2,741)</b>	<b>\$63,453</b>
Net loss	-	-	-	-	-	(52,953 )	-	-	-	-	(52,953 )
Foreign currency translation adjustments	-	-	-	-	-	-	(60 )	-	-	-	(60 )
Stock-based compensation expense	-	-	-	-	4,301	-	-	-	-	-	4,301
Cumulative effect of ASU 2014-09 adoption	-	-	-	-	-	35	-	-	-	-	35
Issuance of common stock in connection with at-the-market offering, net of commissions and issuance costs	4,230	5	(320)	-	27,539	-	-	2,109	-	-	29,653
Sale of common stock in public offering, net of underwriting discounts and	9,091	12	-	-	69,975	-	-	-	-	-	69,987

commissions  
(\$4,500) and  
offering  
expenses  
(\$513)

Exercise of stock options	96	-	-	-	467	-	-	-	-	-	467
<b>Balance at</b>											
<b>September 30, 2018</b>	<b>84,742</b>	<b>\$ 110</b>	<b>-</b>	<b>\$ -</b>	<b>\$ 712,111</b>	<b>\$ (594,504 )</b>	<b>\$ (93 )</b>	<b>\$ -</b>	<b>(200)</b>	<b>\$ (2,741)</b>	<b>\$ 114,883</b>

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

Table of Contents**PROGENICS PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)****(Unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
Cash flows from operating activities:		
Net loss	\$(52,953 )	\$(48,348 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,301	3,124
Depreciation and amortization	1,014	832
Non-cash interest expense	229	172
Deferred income tax	(1,549 )	-
Intangible impairment charge	23,200	-
Change in fair value of contingent consideration liability	(5,900 )	3,300
Other	-	10
Changes in assets and liabilities:		
Accounts receivable	(1,813 )	2,245
Other current assets	(1 )	2,644
Accounts payable	(2,714 )	527
Accrued expenses	(1,874 )	(5,732 )
Other liabilities	218	242
Net cash used in operating activities	(37,842 )	(40,984 )
Cash flows from investing activities:		
Purchases of property and equipment	(595 )	(263 )
Proceeds from sale of fixed assets	-	37
Net cash used in investing activities	(595 )	(226 )
Cash flows from financing activities:		
Net proceeds from public offering of common stock	69,987	-
Net proceeds from issuance of common stock in connection with at-the-market offering	29,653	-
Return of estimated interest payment for noncontrolling interest	-	21
Proceeds from exercise of stock options	467	470
Repayment of debt	(3,368 )	-
Net cash provided by financing activities	96,739	491
Effect of currency rate changes on cash, cash equivalents and restricted cash	(86 )	93
Net decrease in cash, cash equivalents, and restricted cash	58,216	(40,626 )
Cash, cash equivalents, and restricted cash at beginning of period	92,164	140,910
<b>Cash, cash equivalents, and restricted cash at end of period</b>	<b>\$150,380</b>	<b>\$100,284</b>

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets to the total of the same such amounts shown above for the nine months ended September 30, 2018:

<b>Cash, cash equivalents, and restricted cash information</b>	
Cash and cash equivalents at beginning of period	\$90,642
Restricted cash included in long-term assets at the beginning of period	1,522
Cash, cash equivalents, and restricted cash at beginning of period	<b>\$92,164</b>
 Cash and cash equivalents at end of period	 \$148,851
Restricted cash included in long-term assets at the end of period	1,529
Cash, cash equivalents, and restricted cash at end of period	<b>\$150,380</b>

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

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**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”) is an oncology company focused on the development and commercialization of innovative targeted medicines and other technologies to target and treat cancer.

Highlights of our recent progress include:

*AZEDRA® approval.* U.S. Food and Drug Administration (“FDA”) approved the New Drug Application (“NDA”) for AZEDRA (iobenguane I 131) 555 MBq/mL injection for intravenous use. AZEDRA, a radiotherapeutic, is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. AZEDRA is the first and only approved therapy for this indication.

*AZEDRA Launch.* AZEDRA was launched August 1, 2018. Since August, AZEDRA was added to the National Comprehensive Cancer Network® (“NCCN”) Clinical Practice Guidelines in Oncology for Neuroendocrine and Adrenal Tumors v 3.2018. NCCN Guidelines® are widely recognized and used as the standard for clinical policy in oncology by clinicians and payors. Since AZEDRA’s approval by the FDA, it has also been added to four drug compendia: Clinical Pharmacology®; DRUGDEX®; Lexi-Drugs®; and NCCN. These compendia are recognized by private and public payers, including Centers for Medicare and Medicaid Services (“CMS”) as authoritative sources to be considered in determining drug reimbursement. A field-based team of Nuclear Medicine Technologists/Sales Representatives/Medical Science Liaisons and Access Specialists have been in the field since approval assisting centers of excellence and payers in the preparation for utilizing and reimbursing AZEDRA.

*Pipeline Advancement*

We advanced our 1095 program and plan initiate a Phase 2 trial in early 2019. 1095 is a small molecule radiotherapeutic designed to selectively bind to the extracellular domain of prostate specific membrane antigen (“PSMA”). The multicenter, randomized, controlled trial will evaluate the efficacy and safety of 1095 in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) who are PSMA-avid, chemotherapy naïve, and progressed on abiraterone.

We reported topline results from our recently completed Phase 2/3 study of PyL which demonstrated its potential high clinical utility. These results were used to design the pivotal Phase 3 study planned to commence in the fourth quarter.

We reported topline results of our recently completed Phase 3 study in 1404. The Phase 3 trial evaluated the specificity of 1404 imaging to identify patients without clinically significant prostate cancer and sensitivity to identify patients with clinically significant disease. Based on the 1404 data and an assessment of the PSMA-targeted imaging agent commercial landscape, we decided to focus our efforts on our PyL PSMA-targeted PET/CT imaging agent and will not further invest in 1404.

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

#### Strategic partnerships

RELISTOR® (methylnaltrexone bromide) is licensed to Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.). RELISTOR subcutaneous injection and RELISTOR Tablets are approved by the FDA for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.

Bayer AG (“Bayer”) has exclusive worldwide rights to develop and commercialize products using our PSMA antibody technology in combination with Bayer’s alpha-emitting radionuclides. Bayer is developing PSMA TTC, a thorium-227 labeled PSMA-targeted antibody therapeutic. We expect Bayer to initiate a Phase 1 study of PSMA TTC in patients with metastatic castration-resistant prostate cancer by year-end.

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Our current principal sources of revenue from operations are royalty, development and commercial milestones from Bausch and Bayer. Royalty and further milestone payments from Bausch or Bayer depend on success in development and commercialization of RELISTOR and our PSMA antibody technology, respectively, which is dependent on many factors, such as Bausch or Bayer's respective 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 the licensed products.

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 business 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 the operations of our wholly-owned foreign subsidiary, EXINI Diagnostics A.B. ("EXINI"), are conducted at our facility in Lund, Sweden. We operate under a single operating segment, which includes development and commercialization of pharmaceutical products and other technologies to target, diagnose and treat cancer. Our operating segment is regularly evaluated for financial performance by our chief operating decision maker, who is our Chief Executive Officer.

### *Liquidity*

At September 30, 2018, we had \$148.9 million of cash and cash equivalents, an increase of \$58.2 million from \$90.6 million at December 31, 2017. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year from the filing date of this Form 10-Q. 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.

During the third quarter of 2018, we raised net proceeds of \$70.0 million in an underwritten public offering of 9.1 million shares of common stock at a public offering price of \$8.25 per share and an additional \$4.8 million in at-the-market ("ATM") transactions under a controlled equity offering sales agreement ("Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") of 0.6 million shares of common stock at an average selling price of \$8.36 per share. (See **Note 10. Stockholders' Equity** for additional information).

### *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, 2017. 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.

#### *Reclassifications*

On January 1, 2018, we adopted Accounting Standards Update (ASU) No. 2016-18 (“ASU 2016-18”), *Statement of Cash Flows (Topic 230) – Restricted Cash* and ASU No. 2016-15 (“ASU 2016-15”), *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. Accordingly, the condensed consolidated statement of cash flow for the nine months ended September 30, 2017 has been re-casted to conform with the current period presentation under this new guidance.

#### *Principles of Consolidation*

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



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### *Use of Estimates*

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

### *Revenue Recognition*

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09” or the “Topic 606”). The standard provides a single model for revenue arising from contracts with customers and supersedes current revenue recognition guidance. We adopted ASU 2014-09 on January 1, 2018, using the modified retrospective method, for all contracts not completed as of the date of adoption. The adoption of ASU 2014-09 represents a change in accounting principle that will more closely align revenue recognition with the transfer of promised goods or services to the customer. We implemented internal controls in 2017 to ensure we adequately evaluated our contracts and properly assessed the impact of the new accounting standard related to revenue recognition on our financial statements to facilitate adoption on January 1, 2018. There were no significant changes to our internal control over financial reporting due to the adoption of the new standard.

Based on the evaluation of our current contracts, revenue recognition is consistent under ASC 605 *Revenue Recognition* and ASC 606 *Revenue from Contracts with Customers*, except for revenue from variable consideration bonus payments under our software licensing arrangements. The cumulative effect of applying ASU 2014-09 to all contracts that were not completed as of January 1, 2018 was recorded as a post-adoption adjustment of approximately \$35 thousand to the opening balance of accumulated deficit on January 1, 2018, with a corresponding increase to accounts receivable. Subsequent to the adoption of the new standard, variable consideration related to the bonus payments are estimated and recognized when it is probable that a significant reversal of revenue will not occur.

Under this new guidance, we recognize revenue when our customers obtain control of the promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To account for arrangements that are within the scope of this new guidance, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy our performance obligations.

For contracts determined to be within the scope of Topic 606, we assess the goods or services promised within each contract for the purpose of identifying them as performance obligations. We must apply judgement in assessing whether each promised good or service is distinct. If a promised good or service is not distinct, we will combine that

good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their estimated fair value, which requires significant judgment. Variable consideration, which is estimated using the expected value method or the most likely amount method, is included in the transaction price only if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur.

For arrangements that include development, regulatory or sales milestone payments, we evaluate whether the milestones are probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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The following table summarizes our revenue streams from contracts with customers for the three and nine months ended September 30, 2018:

	<b>Three months ended September 30, 2018</b>	<b>Nine months ended September 30, 2018</b>
Royalty income	\$ 5,169	\$ 11,757
Other revenue	148	627
<b>Total revenue</b>	<b>\$ 5,317</b>	<b>\$ 12,384</b>

Royalty income - represents revenue from the sales-based royalties under our intellectual property licensing arrangements and is recognized upon net sales of the licensed products.

Other revenue – represents revenue from upfront payments (fixed consideration) and development and sales milestones, sublicense payments, support and service payments and sales-based bonus payments (variable consideration) under our licensing or software arrangements. The fixed consideration will be recognized as revenue at the time when the transfer of know-how is completed. The variable consideration will be estimated using the most likely amount method and recognized only when we have “a high degree of confidence” that revenue will not be reversed in a subsequent reporting period. The other revenue also includes revenue from product sales of research reagents, that is recognized upon shipment to the end customer (i.e. control of the product is deemed to be transferred).

We had receivable contract balances of \$5.8 million and \$4.0 million as of September 30, 2018 and December 31, 2017, respectively, primarily related to the royalty revenue stream (see **Note 5. Accounts Receivable**).

*Restricted Cash*

Restricted cash included in long-term assets of \$1.5 million at September 30, 2018 and December 31, 2017, represents collateral for a letter of credit securing a lease obligation. We believe the carrying value of this asset approximates fair value.

*Foreign Currency Translation*

Our international subsidiaries generally consider 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 loss, and the cumulative effect is included in the stockholders’ equity section of our condensed consolidated balance sheets. Realized gains and losses denominated in foreign currencies 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, 2018 or 2017.

### *Property and Equipment*

Property and equipment is recorded at historical cost, net of accumulated depreciation and amortization of \$2.5 million and \$1.7 million as of September 30, 2018 and December 31, 2017, respectively. The following table summarizes our property and equipment (in thousands):

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
Machinery and equipment	\$ 3,002	\$ 2,516
Leasehold improvements	1,734	1,734
Computer equipment	719	714
Furniture and fixtures	878	874
Construction in progress	97	-
Property and equipment, gross	6,430	5,838
Less - accumulated depreciation	(2,453 )	(1,716 )
<b>Property and equipment, net</b>	<b>\$ 3,977</b>	<b>\$ 4,122</b>

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**Note 2. New Accounting Pronouncements**

*Recently Adopted*

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09” or the “Topic 606”). The standard provides a single model for revenue arising from contracts with customers and supersedes current revenue recognition guidance. We adopted ASU 2014-09 on January 1, 2018, using the modified retrospective method, for all contracts not completed as of the date of adoption. (See **Note 1. Summary of Significant Accounting Policies** for additional information)

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 type 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. We adopted this standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial statements, as we do not have any equity investments.

In November 2016, the FASB issued ASU No. 2016-18 (“ASU 2016-18”), *Statement of Cash Flows (Topic 230) – Restricted Cash*. For entities that have restricted cash and are required to present a statement of cash flows, ASU 2016-18 changes the cash flow presentation for restricted cash. We adopted this standard on January 1, 2018. Accordingly, the condensed consolidated statement of cash flow for the nine months ended September 30, 2017 has been re-casted to conform with the current period presentation under this new guidance.

In January 2017, the FASB issued ASU No. 2017-01 (“ASU 2017-01”), *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The standard narrows the application of when an integrated set of assets and activities is considered a business and provides a framework to assist entities in evaluating whether both an input and a substantive process are present to be considered a business. We adopted this standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04 (“ASU 2017-04”), *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. The standard simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount. We adopted this standard on

January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial statements.

*Not Yet Adopted*

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, with early adoption permitted. We are currently evaluating the impact of this new standard on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)* (“ASU 2018-13”). The updated guidance improves the disclosure requirements on fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. We are currently assessing the timing and impact of adopting the updated provisions.

**Note 3. Net Loss Per Share**

Our basic net loss per share amounts have been computed by dividing net loss by the weighted-average number of common shares outstanding during the period. For the three and nine months ended September 30, 2018 and 2017, we reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive.

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The calculations of net loss per share, basic and diluted, are as follows (amounts in thousands, except per share data):

	<b>Net Loss</b>	<b>Weighted-Average Shares</b>	<b>Per Share Amount</b>
	<b>(Numerator)</b>	<b>(Denominator)</b>	
<b>Three months ended September 30, 2018</b>			
Basic and diluted	\$ (24,357 )	80,325	\$ (0.30 )
<b>Nine months ended September 30, 2018</b>			
Basic and diluted	\$ (52,953 )	75,648	\$ (0.70 )
<b>Three months ended September 30, 2017</b>			
Basic and diluted	\$ (15,352 )	70,270	\$ (0.22 )
<b>Nine months ended September 30, 2017</b>			
Basic and diluted	\$ (48,348 )	70,233	\$ (0.69 )

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 loss per share (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Stock options	2,775	3,061	3,277	1,989
Contingent consideration liability	1,738	2,378	1,738	2,378
<b>Total securities excluded</b>	<b>4,513</b>	<b>5,439</b>	<b>5,015</b>	<b>4,367</b>

**Note 4. 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, restricted cash, accounts receivable, other current assets, other assets, accounts payable and accrued expenses approximated their fair values as of September 30, 2018 and December 31, 2017.

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*).



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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, 2018		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Balance at September 30, 2018			
<b>Assets:</b>				
Money market funds	\$ 145,515	\$ 145,515	\$ -	\$ -
<b>Total assets</b>	<b>\$ 145,515</b>	<b>\$ 145,515</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Liabilities:</b>				
Contingent consideration liability	\$ 10,900	\$ -	\$ -	\$ 10,900
<b>Total liabilities</b>	<b>\$ 10,900</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 10,900</b>

		Fair Value Measurements at December 31, 2017		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Balance at December 31, 2017			
<b>Assets:</b>				
Money market funds	\$ 87,231	\$ 87,231	\$ -	\$ -
<b>Total assets</b>	<b>\$ 87,231</b>	<b>\$ 87,231</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Liabilities:</b>				
Contingent consideration liability	\$ 16,800	\$ -	\$ -	\$ 16,800
<b>Total liabilities</b>	<b>\$ 16,800</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 16,800</b>

The contingent consideration liability of \$10.9 million as of September 30, 2018 represents the estimated fair value of the future potential milestone payments to former MIP stockholders (shown in the tables below).

Milestone payments due upon first commercial sale (in thousands):

<b>Program</b>	<b>Consideration</b>	<b>Form of Payment at Progenics' Option</b>
AZEDRA	\$ 8,000	Cash or Progenics common stock
1404	10,000	Cash or Progenics common stock
1095	5,000	Cash or Progenics common stock
	<b>\$ 23,000</b>	

Net sales milestone payments due upon first achievement of specified net sales target in any single calendar year across all MIP-related programs (in thousands):

	<b>Consideration</b>	<b>Form of Payment at Progenics' Option</b>
\$30 million	\$ 5,000	Cash or Progenics common stock
\$60 million	5,000	Cash or Progenics common stock
\$100 million	10,000	Cash or Progenics common stock
\$250 million	20,000	Cash or Progenics common stock
\$500 million	30,000	Cash or Progenics common stock
	<b>\$ 70,000</b>	

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.

Significant changes in any of the probabilities of success or the probabilities as to the periods in which milestones will be achieved, would result in a significantly higher or lower fair value measurement. 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.

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The following table summarizes quantitative information and assumptions pertaining to the fair value measurement of the Level 3 inputs at September 30, 2018 and December 31, 2017 (in thousands). The decrease in the contingent consideration liability of \$8.0 million and \$5.9 million during the three and nine months ended September 30, 2018, respectively, was primarily attributable to a decrease in the sales projections and probability of success for 1404, following results from the recently completed Phase 3 trial, whereby only one of the co-primary endpoints was met, partially offset by higher estimated probability of success of AZEDRA and a decrease in the discount period used to calculate the present value of the contingent consideration liability.

	<b>Fair Value at September 30, 2018</b>	<b>Valuation Technique</b>	<b>Unobservable Input</b>	<b>Assumption</b>
<b>Contingent Consideration Liability:</b>				
AZEDRA commercialization	\$ 7,000	Probability adjusted discounted cash flow model	Probability of success	90%
			Period of expected milestone achievement	2019
			Discount rate	10%
1095 commercialization	400	Probability adjusted discounted cash flow model	Probability of success	16%
			Period of expected milestone achievement	2025
			Discount rate	10%
Net sales targets	3,500	Monte-Carlo simulation	Probability of success	16% - 90%
			Discount rate	10%
<b>Total</b>	<b>\$ 10,900</b>			

	<b>Fair Value at December 31, 2017</b>	<b>Valuation Technique</b>	<b>Unobservable Input</b>	<b>Assumption</b>
<b>Contingent Consideration Liability:</b>				
AZEDRA commercialization	\$ 5,500	Probability adjusted discounted cash flow model	Probability of success	72%
			Period of expected milestone achievement	2018
			Discount rate	10%
1404 commercialization	4,500	Probability adjusted discounted cash flow model	Probability of success	59%
			Period of expected milestone achievement	2020

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1095 commercialization	400	Probability adjusted discounted cash flow model	Discount rate	10%	
			Probability of success	16%	
			Period of expected milestone achievement	2025	
Net sales targets	6,400	Monte-Carlo simulation	Discount rate	10%	
			Probability of success	16% -	72%
			Discount rate	10%	
<b>Total</b>	<b>\$ 16,800</b>				

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

<b>Liability - Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</b>				
		<b>Three Months Ended September 30, 2018</b>		<b>Nine Months Ended September 30, 2018</b>
		<b>2017</b>		<b>2017</b>
Balance at beginning of period		\$18,900	\$16,800	\$16,800 \$14,200
Fair value change included in net loss		(8,000 )	700	(5,900 ) 3,300
Balance at end of period		<b>\$10,900</b>	<b>\$17,500</b>	<b>\$10,900 \$17,500</b>
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		<b>\$ (8,000 )</b>	<b>\$ 700</b>	<b>\$ (5,900 ) \$ 3,300</b>

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Our accounts receivable represent amounts due to us from royalties, collaborators, and, to a small extent, sales of research reagents, and consisted of the following at September 30, 2018 and December 31, 2017 (in thousands):

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
Royalties	\$ 5,169	\$ 3,683
Other	652	289
<b>Accounts receivable, net</b>	<b>\$ 5,821</b>	<b>\$ 3,972</b>

**Note 6. 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.

Based on the results from the recently completed 1404 Phase 3 trial, whereby only one of the co-primary endpoints was met, we changed our third quarter 2018 assumptions of potential future sales projections, resulting in a \$23.2 million impairment of the 1404 indefinite-lived assets fair value. The corresponding non-cash impairment charge was recorded as part of operating expenses in the condensed consolidated statements of operations.

In addition, upon the FDA approval of AZEDRA on July 30, 2018, the \$4.9 million indefinite-lived intangible asset related to AZEDRA was reclassified as a finite-lived intangible asset and is now being amortized over the estimated

useful life of seven years. The related amortization expense is recorded as part of selling, general and administrative expenses in the condensed consolidated statements of operations.

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, 2018 or 2017.

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

	<b>Goodwill</b>	<b>IPR&amp;D</b>	<b>Other Intangible Assets</b>
Balance at January 1, 2018	\$ 13,074	\$28,700	\$ 1,669
Impairment	-	(23,200)	-
Amortization expense	-	(117 )	(159 )
<b>Balance at September 30, 2018</b>	<b>\$ 13,074</b>	<b>\$5,383</b>	<b>\$ 1,510</b>

	<b>Goodwill</b>	<b>IPR&amp;D</b>	<b>Other Intangible Assets</b>
Balance at January 1, 2017	\$ 13,074	\$28,700	\$ 1,881
Amortization expense	-	-	(159 )
<b>Balance at September 30, 2017</b>	<b>\$ 13,074</b>	<b>\$28,700</b>	<b>\$ 1,722</b>

Table of Contents**Note 7. 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, 2018 and December 31, 2017 (in thousands):

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
Accrued clinical trial costs	\$ 2,163	\$ 2,570
Accrued payroll and related costs	2,424	2,400
Accrued consulting and service fee expenses	1,241	1,860
Accrued legal and professional fees	1,114	1,022
Accrued contract manufacturing costs	252	666
Other	456	1,037
<b>Accrued expenses</b>	<b>\$ 7,650</b>	<b>\$ 9,555</b>

**Note 8. Commitments and Contingencies**

We are or may be involved in 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. 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.

**Abbreviated New Drug Application Litigations*****RELISTOR Subcutaneous Injection - Mylan and Actavis*****Paragraph IV Certifications**

On or about October 6, 2015, November 20, 2015, December 22, 2015, and December 23, 2015, Progenics, Salix Pharmaceuticals, Inc. (“Salix”) and Wyeth LLC (“Wyeth”) received four separate notifications of a Paragraph IV certification for RELISTOR (methylnaltrexone bromide) subcutaneous injection, for certain patents that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, also known as “the Orange Book.” The certifications 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 or about October 27, 2015, January 5, 2016, and January 8, 2016, Progenics, Salix and Wyeth received three separate notifications of a Paragraph IV certification for certain patents for RELISTOR (methylnaltrexone bromide) subcutaneous injection, for certain patents that are listed in the FDA’s Orange Book. The certifications resulted from the filing by Actavis LLC of an 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.

#### District Court Actions

Progenics, Salix, Valeant (now Bausch Health Companies Inc., “Bausch”), and Wyeth filed suit against Mylan Pharmaceuticals, Inc. and Mylan Inc. in the District of New Jersey on November 19, 2015 (2:15-cv-8180-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, and 8,822,490 based upon Mylan Pharmaceutical Inc.’s filing of its ANDA seeking to obtain approval to market a generic version of RELISTOR vials before some or all of these patents expire. On February 4, 2016, Progenics, Salix, Bausch, and Wyeth filed an amended complaint, identifying Mylan Laboratories Ltd. as an additional Defendant, and further seeking declaratory judgment of infringement of U.S. Patent No. 9,180,125. Progenics, Salix, Bausch, and Wyeth filed suit against Mylan Pharmaceuticals, Inc., Mylan Laboratories Ltd., and Mylan Inc. in the District of New Jersey on January 4, 2016 (2:16-cv-00035-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, and 8,822,490 based upon Mylan Pharmaceutical Inc.’s filing of its ANDA seeking to obtain approval to market a generic version of RELISTOR prefilled syringes before some or all of these patents expire. On January 25, 2016, Progenics, Salix, Bausch, and Wyeth filed an amended complaint, further seeking declaratory judgment of infringement of U.S. Patent No. 9,180,125. Progenics, Salix, Bausch, and Wyeth filed suit against Mylan Pharmaceuticals, Inc., Mylan Laboratories Ltd., and Mylan Inc. in the District of New Jersey on September 1, 2017 (2:17-cv-06714-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent No. 9,669,096 based upon Mylan Pharmaceutical Inc.’s filing of ANDAs seeking to obtain approval to market generic versions of RELISTOR vials and prefilled syringes before the patents expires. On September 18, 2017, Progenics, Salix, Bausch, and Wyeth filed an amended complaint, further seeking declaratory judgment of infringement of U.S. Patent No. 9,492,445.



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Progenics, Salix, Bausch, and Wyeth filed suit against Actavis LLC, Actavis, Inc., Actavis Elizabeth LLC, and Allergan PLC fka Actavis PLC in the District of New Jersey on November 30, 2015 (2:15-cv-08353-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, and 8,822,490 based upon Actavis LLC's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR prefilled syringes before some or all of these patents expire. On February 18, 2016, Progenics, Salix, Bausch, and Wyeth filed an amended complaint, further seeking declaratory judgment of infringement of U.S. Patent No. 9,180,125. Progenics, Salix, Bausch, and Wyeth filed suit against Actavis LLC, Actavis, Inc., Actavis Elizabeth LLC, and Allergan PLC fka Actavis PLC in the District of New Jersey on February 18, 2016 (2:16-cv-00889-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, and 8,822,490 based upon Actavis LLC's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR vials before some or all of these patents expire. Progenics, Salix, Bausch, and Wyeth filed suit against Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. in the District of New Jersey on August 18, 2017 (2:17-cv-07206-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 9,669,096 and 9,492,445 based upon Actavis LLC's filing of ANDAs seeking to obtain approval to market generic versions of RELISTOR vials and prefilled syringes before the patents expires.

The 2:15-cv-8180-SRC-CLW, 2:16-cv-00035-SRC-CLW, 2:15-cv-08353-SRC-CLW, and 2:16-cv-00889-SRC-CLW actions were consolidated into a single action in the District of New Jersey (2:15-cv-08180-SRC-CLW). On May 1, 2018, the Court granted Plaintiffs' motion for partial summary judgment as to the validity of claim 8 of U.S. Patent No. 8,552,025. On May 23, 2018, the Court entered an order for final judgment under Fed. R. Civ. P. 54(b) in favor of Plaintiffs and against Mylan and Actavis as to claim 8 of the '025 patent.

The 2:17-cv-06714-SRC-CLW and 2:17-cv-07206-SRC-CLW were consolidated into a single action in the District of New Jersey (2:17-cv-06714-SRC-CLW). Litigation in this action is underway and is currently in the discovery phase. This action has been consolidated for purposes of trial only with the 2:15-cv-8180 action.

Settlement Agreement (Actavis)

On May 25, 2018, Progenics, Bausch, Salix, Wyeth (Progenics, Bausch and Salix, each "Plaintiff" and collectively "Plaintiffs") and Actavis LLC ("Actavis") entered into a Settlement and License Agreement (the "Agreement") relating to Civil Action No. 2:15-cv-08180 and Civil Action No. 2:17-cv-06714. The following is a summary of the material terms of the Agreement. The Agreement provides for a full settlement and release by both Plaintiffs and Actavis of all claims that were or could have been asserted in the District Court Cases and all resulting damages or other remedies. Plaintiffs and Actavis have agreed to and, in fact, filed a Stipulated Consent Judgment and Injunction after the execution of the Agreement. Plaintiffs and Actavis have further acknowledged and agreed that the 30-month stay imposed by the FDA in relation to the approval of Actavis' ANDAs for the Actavis Products (the "Actavis ANDAs") should be terminated.

Under the Agreement, Plaintiffs grant Actavis a non-exclusive, royalty-free, non-transferable, non-sublicensable, limited license under the Patents-In-Suit to make, import, and sell each of the Actavis Products in the U.S. (the “License”) beginning on the earliest of (a) January 1, 2028; (b) for each of the Actavis Products, if Actavis is a “First Applicant” (as defined in 21. U.S.C. § 355(j)(5)(B)(iv)(II)) and has not forfeited, relinquished or otherwise waived its 180-day exclusivity, 180 days prior to the date on which an entity not a First Applicant is permitted to commercially sell such Actavis Product in the U.S. under authorization from Plaintiffs; (c) for each of the Actavis Products, if Actavis either is not a First Applicant or otherwise has forfeited, relinquished or otherwise waived its 180-day exclusivity, the earlier of (i) 181 days after any third party that is a First Applicant markets a corresponding single-dose vial or pre-filled syringe that has been FDA approved or submitted for approval under an ANDA as a generic version of RELISTOR® Injection for subcutaneous use (the “Generic Products”) in the U.S., or (ii) the date on which a third party that is either not a First Applicant or otherwise has waived its 180-day exclusivity markets, or is first authorized by Plaintiffs to begin marketing, such Generic Product; (d) for each of the Actavis Products, the date on which a third party that has sought or received approval from the FDA under a “New Drug Application” (as defined in the US Federal Drug and Cosmetic Act and regulations promulgated thereunder) (“NDA”) for a corresponding single-dose vial or pre-filled syringe of methylnaltrexone bromide for subcutaneous use for which RELISTOR® Injection is the listed drug (a “Section 505(b)(2) Applicant”) markets or is first authorized by Plaintiffs to begin marketing such corresponding product; (e) for each of the Actavis Products, the date on which a corresponding generic version of the single-dose vial or pre-filled syringe of methylnaltrexone bromide for subcutaneous use approved under NDA No. 021964 for RELISTOR® Injection that is marketed or intended for marketing in the U.S. without the RELISTOR® trademark (an “Authorized Generic Product”) is first marketed in the U.S. by a third party; or (f) the earlier of (i) the date on which a final court decision is entered holding that each of the unexpired claims of the Patents-In-Suit are invalid and/or unenforceable, or (ii) the date on which the Patents-In-Suit have expired, been permanently abandoned, or delisted from the Orange Book. The Agreement also gives Actavis a limited right to grant sublicenses to its affiliates for certain pre-marketing activities.

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Federal Circuit Appeal

On May 25, 2018, Mylan filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit. The matter is currently pending on appeal at the Federal Circuit.

On July 9, 2018, Bausch and Salix filed a motion to disqualify Katten Muchin Rosenman LLP as counsel for Mylan. On July 17, 2018, an order was issued staying the briefing on the merits of Mylan's appeal pending the disposition of the motion to disqualify. Oral argument was held on September 12, 2018. A decision on the motion to disqualify is currently pending.

***RELISTOR Subcutaneous Injection - Par***

Paragraph IV Certification

On or about July 15, 2017, Progenics, Salix and Wyeth received notification of a Paragraph IV certification for RELISTOR (methylnaltrexone bromide) subcutaneous injection, for certain patents that are listed in the FDA's Orange Book. The certification resulted from the filing by Par Sterile Products, LLC of an 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.

District Court Actions

Progenics, Salix, Bausch, and Wyeth filed suit against Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Endo International plc in the District of New Jersey on August 25, 2017 (2:17-cv-06449-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, 9,180,125, and 9,669,096 based upon Par Sterile Product's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR vials before some or all of these patents expire.

Progenics, Salix, Bausch, and Wyeth filed suit against Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Endo International plc in the Southern District of New York on August 25, 2017 (1:17-cv-06557-PAE) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, 9,180,125, and 9,669,096 based upon Par Sterile Product's filing of an ANDA seeking to obtain approval to market a generic version of

RELISTOR vials before some or all of these patents expire. This action was voluntarily dismissed on November 30, 2017.

Settlement Agreement

On May 10, 2018, Progenics, Bausch, Salix, Wyeth and Par Sterile Products, LLC (“Par Sterile”) and Par Pharmaceutical, Inc. (“Par Pharmaceutical” and, together with Par Sterile, “Par”) entered into a Settlement and License Agreement (the “Agreement”) relating to Civil Action No. 17-06449-SRC-CLW (the “District Court Case”). The following is a summary of the material terms of the Agreement.

The Agreement provides for a full settlement and release by both Plaintiffs and Par of all claims that were or could have been asserted in the District Court Case and all resulting damages or other remedies. Plaintiffs and Par have agreed to and, in fact, filed a Stipulated Consent Judgment and Injunction after the execution of the Agreement. Plaintiffs and Par have further acknowledged and agreed that the 30-month stay imposed by the FDA in relation to the approval of Par’s ANDA for the Par Products (the “Par ANDA”) should be terminated.

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Under the Agreement, Plaintiffs grant Par a non-exclusive, royalty-free, non-transferable, non-sublicensable, limited license under the Patents-In-Suit to make, import, and sell the Par Products in the U.S., or make outside the U.S. solely for importation into the U.S. (the “License”) beginning on the earliest of (i) September 30, 2030; (ii) for either of the Par Products, one hundred eighty-one (181) days after any third party who is the “First Applicant” (as defined in 21 U.S.C. § 355(j)(5)(B)(iv)(II)) markets a single-dose vial or pre-filled syringe that has been FDA approved or submitted for approval under an ANDA as a generic version of RELISTOR® Injection for subcutaneous use (the “Generic Products”); (iii) for either of the Par Products, the date on which a non-First Applicant third party markets an authorized generic (under the RELISTOR® New Drug Application (“NDA”) but without the RELISTOR® trademark) single-dose vial or pre-filled syringe of methylnaltrexone bromide for subcutaneous use in the U.S.; (iv) for either of the Par Products, the date on which a third party who is not a First Applicant (or who is a First Applicant who has forfeited or otherwise waived its 180-day exclusivity) markets or is first authorized by Plaintiffs to market the Generic Products in the U.S.; (v) the date on which a final court decision is entered holding that each of the asserted claims against Par in the District Court Case from the Patents-In-Suit are invalid and/or unenforceable, or not infringed by the single-dose vial Par Product; or (vi) the date on which the Patents-In-Suit have expired, been permanently abandoned or delisted from the FDA’s Orange Book. Plaintiffs have also granted to Par a limited pre-commercialization license to manufacture and/or import the Par Products into the U.S. starting one hundred fifty (150) days prior to the effective date of the License solely to the extent reasonably necessary to enable Par to market the Par Products in the U.S. on or after the effective date of the License.

## ***RELISTOR Tablets - Actavis***

### Paragraph IV Certifications

On or about October 24, 2016 and October 24, 2017, Progenics, Salix, Bausch and Wyeth received two separate notifications of a Paragraph IV certification for RELISTOR (methylnaltrexone bromide) tablets, for certain patents that are listed in the FDA’s Orange Book. The certification resulted from the filing by Actavis Laboratories FL, Inc. (“Actavis”) of an ANDA with the FDA, challenging such patents for RELISTOR tablets and seeking to obtain approval to market a generic version of RELISTOR tablets before some or all of these patents expire.

### District Court Actions

Progenics, Salix, Bausch, and Wyeth filed suit against Actavis Laboratories FL, Inc., Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. in the District of New Jersey on December 6, 2016 (2:16-cv-09038-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,420,663, 8,524,276, 8,956,651, 9,180,125, and 9,314,461 based upon Actavis’s filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before some or all of these patents expire.

## Edgar Filing: PROGENICS PHARMACEUTICALS INC - Form 10-Q

Progenics, Salix, Bausch, and Wyeth filed suit against Actavis Laboratories FL, Inc., Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. in the District of New Jersey on December 8, 2017 (2:17-cv-12857-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent Nos. 9,724,343 and 9,492,445 based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before some or all of these patents expire.

The 2:16-cv-09038-SRC-CLW and 2:17-cv-12857-SRC-CLW actions were consolidated into a single action in the District of New Jersey (2:16-cv-09038-SRC-CLW). Litigation is underway and is currently in the expert discovery phase.

### **European Opposition Proceedings**

In addition to the above described ANDA notifications, in October 2015, Progenics received notices of opposition to three European patents relating to methylnaltrexone. Notices of opposition against EP1615646 were filed on September 24, 2015 separately by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH. Notices of opposition against EP2368553 were filed on September 29, 2015 and September 30, 2015 by Fresenius Kabi Deutschland GmbH and Actavis Group PTC ehf, respectively. Notices of opposition against EP2368554 were filed on September 24, 2015 separately by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH.

On May 11, 2017, the opposition division provided notice that EP2368553 will be revoked. On June 28, 2017, the opposition division provided notice that EP1615646 will be revoked. On July 4, 2017, the opposition division provided notice that EP2368554 will be revoked. Each of these matters are on appeal with the European Patent Office.

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

**Note 9. Non-Recourse Long-Term Debt, Net**

On November 4, 2016, through a new wholly-owned subsidiary MNTX Royalties Sub LLC (“MNTX Royalties”), we entered into a \$50.0 million loan agreement (the “Royalty-Backed Loan”) with a fund managed by HealthCare Royalty Partners III, L.P. (“HCRP”). 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 Bausch. 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, payments of interest and principal, if any, are 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 were 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% of RELISTOR royalty payments received since the immediately-preceding payment date in excess of accrued interest on the loan are 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 and if HCRP so elects, 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.

In connection with the Royalty-Backed Loan, the debt issuance costs have been recorded as a debt discount in our consolidated balance sheets and are being amortized and recorded as interest expense throughout the life of the loan using the effective interest method.

The following tables summarize the components of the Royalty-Backed Loan in our condensed consolidated financial statements for the periods presented (in thousands):

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
<b>Condensed Consolidated Balance Sheets</b>		
Outstanding principal balance, current portion	\$ 8,551	\$ 2,686
Unamortized debt discount, current portion	(335 )	(241 )
<b>Current portion of debt, net</b>	<b>\$ 8,216</b>	<b>\$ 2,445</b>
Outstanding principal balance, long-term portion	\$ 38,834	\$ 48,066
Unamortized debt discount, long-term portion	(502 )	(824 )
<b>Long-term debt, net</b>	<b>\$ 38,332</b>	<b>\$ 47,242</b>

	<b>Three Months Ended September 30, 2018 2017</b>		<b>Nine Months Ended September 30, 2018 2017</b>	
<b>Condensed Consolidated Statements of Operations</b>				
Interest expense	\$1,154	\$1,205	\$3,535	\$3,603
Non-cash interest expense	92	62	229	172
<b>Total interest expense included in interest (expense) income, net</b>	<b>\$1,246</b>	<b>\$1,267</b>	<b>\$3,764</b>	<b>\$3,775</b>

As of September 30, 2018, we were in compliance with all material covenants under the Royalty-Backed Loan and there was no material adverse change in our business, operations, or financial conditions, as defined in the loan agreement.

## **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.



Table of Contents*Shelf Registration*

During the first quarter of 2017, we filed a shelf registration statement on Form S-3 (File No. 333-215454) that permitted: (a) the offering, issuance and sale of up to a maximum aggregate offering price of \$250 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the \$250 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75 million of our common stock under our sales agreement with Cantor in one or more ATM offerings. During the third quarter of 2018, we raised \$70.0 million, net of underwriting discounts and commissions and offering expenses, in an underwritten public offering of 9.1 million shares of common stock at a public offering price of \$8.25 per share, and we sold a total of 0.6 million shares of our common stock in ATM transactions under the sales agreement for net proceeds, after deducting commissions and other transaction costs, of approximately \$4.8 million at an average selling price of \$8.36 per share.

On October 12, 2018, we filed a new shelf registration statement on Form S-3 (File No. 333-227805), which was declared effective by the SEC on October 24, 2018. The new shelf registration replaced our prior shelf registration statement, pursuant to which no additional securities will be offered or sold. The new shelf registration statement permits: (a) the offering, issuance and sale of up to a maximum aggregate offering price of \$250 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the \$250 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75 million of our common stock under our sales agreement with Cantor in one or more ATM offerings. In addition, in October 2018 we entered into a new sales agreement with Cantor, as sales agent, which replaced the previous sales agreement from January 2017. Pursuant to the new sales agreement, we may offer and sell through Cantor, from time to time, shares of our common stock up to an aggregate offering price of \$75 million. All offers and sales under the sales agreement have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC.

*Accumulated Other Comprehensive Loss*

The following table summarizes the components of AOCL at September 30, 2018 (in thousands):

	<b>Foreign Currency Translation</b>	<b>AOCL</b>
Balance at January 1, 2018	\$ (33 )	\$ (33 )
Foreign currency translation adjustment	(60 )	(60 )
Balance at September 30, 2018	\$ (93 )	\$ (93 )

We did not have any reclassifications out of AOCL to losses during the nine months ended September 30, 2018 or 2017.

## **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”), which authorized the issuance of 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 was terminated in June 2018 at the time the 2018 Stock Incentive Plan was approved. Shares available for new awards under the 2005 Plan at the time of termination became available for awards under the 2018 Stock Incentive Plan. Options granted before termination of the 2005 Plan will continue to remain outstanding until exercised, cancelled or expired.

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The 2018 Stock Incentive Plan (the “2018 Plan”), pursuant to which we are authorized to issue up to 4,800,000 shares of common stock covering several different types of awards, including stock options, restricted shares, stock appreciation rights, performance shares, and phantom stock. The 2018 Plan will terminate on March 27, 2028.

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, 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, 2018 (in thousands, except per share data or as otherwise noted):

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life</b>
Outstanding at January 1, 2018	5,535	\$ 7.25	6.04
Granted	1,552	\$ 6.94	
Exercised	(96 )	\$ 4.85	
Cancelled	(331 )	\$ 8.06	
Expired	(255 )	\$ 16.07	
<b>Outstanding at September 30, 2018</b>	<b>6,405</b>	<b>\$ 6.81</b>	<b>6.32</b>
<b>Exercisable at September 30, 2018</b>	<b>4,189</b>	<b>\$ 6.42</b>	<b>4.99</b>
<b>Vested and expected to vest at September 30, 2018</b>	<b>5,942</b>	<b>\$ 6.76</b>	<b>6.10</b>

The weighted-average fair value of options granted during the three and nine months ended September 30, 2018 was \$4.38 and \$4.57 per share, respectively and during the three and nine months ended September 30, 2017 was \$4.04 and \$7.11 per share, respectively.

The total intrinsic value (the excess of the market price over the exercise price) was approximately \$3.3 million for stock options outstanding, \$2.9 million for stock options exercisable, and \$3.3 million for stock options vested and expected to vest as of September 30, 2018. The total intrinsic value for stock options exercised during the three and nine months ended September 30, 2018 was approximately \$173 thousand for both periods, and during the three and nine months ended September 30, 2017 was approximately \$2 thousand and \$233 thousand, respectively.

#### *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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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.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Risk-free interest rate	2.81 %	1.82 %	2.71 %	2.17 %
Expected life (in years)	5.23	5.19	6.68	6.76
Expected volatility	62 %	74 %	69 %	72 %
Expected dividend yield	--	--	--	--

Stock-based compensation expense for the three and nine months ended September 30, 2018 and 2017 was recorded in our condensed consolidated statement of operations as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Research and development expenses	\$515	\$380	\$1,492	\$941
Selling, general and administrative expenses	608	555	2,809	2,183
<b>Total stock-based compensation expense</b>	<b>\$1,123</b>	<b>\$935</b>	<b>\$4,301</b>	<b>\$3,124</b>

At September 30, 2018, unrecognized stock-based compensation expense related to stock options was approximately \$6.4 million and is expected to be recognized over a weighted-average period of approximately 2.2 years.

**Note 12. Income Taxes**

We account for income taxes using the liability method in accordance with ASC 740 (Topic 740, *Income Taxes*). Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Income tax expense or benefit related to items not characterized as ordinary income or expense is recognized as a discrete item when incurred.

During the three and nine months ended September 30, 2018, we reduced our deferred tax liability and recorded income tax benefit of \$1.5 million, primarily related to the impairment of an indefinite-lived intangible asset.

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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, 2017. 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; clinical trial data on our products and product candidates will be unfavorable; our products will not receive marketing approval from regulators or, if approved, do not gain sufficient market acceptance to justify development and commercialization costs; the sales of RELISTOR® and other products by our partners and the revenue and income generated for us thereby may not meet expectations; our commercial launch of AZEDRA® may not meet revenue and income 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 AZEDRA or 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.*



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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 are an oncology company focused on the development and commercialization of innovative targeted medicines and other technologies to target and treat cancer.

Highlights of our recent progress include:

*AZEDRA® approval.* U.S. Food and Drug Administration (“FDA”) approved the New Drug Application (“NDA”) for AZEDRA (iobenguane I 131) 555 MBq/mL injection for intravenous use. AZEDRA, a radiotherapeutic, is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. AZEDRA is the first and only approved therapy for this indication.

*AZEDRA Launch.* AZEDRA was launched August 1, 2018. Since August, AZEDRA was added to the National Comprehensive Cancer Network® (“NCCN”) Clinical Practice Guidelines in Oncology for Neuroendocrine and Adrenal Tumors v 3.2018. NCCN Guidelines® are widely recognized and used as the standard for clinical policy in oncology by clinicians and payors. Since AZEDRA’s approval by the FDA, it has also been added to four drug compendia: Clinical Pharmacology®; DRUGDEX®; Lexi-Drugs®; and NCCN. These compendia are recognized by private and public payers, including Centers for Medicare and Medicaid Services (“CMS”) as authoritative sources to be considered in determining drug reimbursement. A field-based team of Nuclear Medicine Technologists/Sales Representatives/Medical Science Liaisons and Access Specialists have been in the field since approval assisting centers of excellence and payers in the preparation for utilizing and reimbursing AZEDRA.

### *Pipeline Advancement*

We advanced our 1095 program and plan initiate a Phase 2 trial in early 2019. 1095 is a small molecule radiotherapeutic designed to selectively bind to the extracellular domain of prostate specific membrane antigen (“PSMA”). The multicenter, randomized, controlled trial will evaluate the efficacy and safety of 1095 in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) who are PSMA-avid, chemotherapy naïve, and progressed on abiraterone.

We reported topline results from our recently completed Phase 2/3 study of PyL which demonstrated its potential high clinical utility. These results were used to design the pivotal Phase 3 study planned to commence in the fourth quarter.

We reported topline results of our recently completed Phase 3 study in 1404. The Phase 3 trial evaluated the specificity of 1404 imaging to identify patients without clinically significant prostate cancer and sensitivity to identify patients with clinically significant disease. Based on the 1404 data and an assessment of the PSMA-targeted imaging agent commercial landscape, we decided to focus our efforts on our PyL PSMA-targeted PET/CT imaging agent and will not further invest in 1404.

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

#### Strategic partnerships

RELISTOR® (methylnaltrexone bromide) is licensed, to Salix Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.). RELISTOR subcutaneous injection and RELISTOR Tablets are approved by the FDA for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.

Bayer AG (“Bayer”) has exclusive worldwide rights to develop and commercialize products using our PSMA antibody technology in combination with Bayer’s alpha-emitting radionuclides. Bayer is developing PSMA TTC, a thorium-227 labeled PSMA-targeted antibody therapeutic. We expect Bayer to initiate a Phase 1 study of PSMA TTC in patients with metastatic castration-resistant prostate cancer by year-end.

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<b>Product / Candidate</b>	<b>Description</b>	<b>Status</b>
<b>Ultra-Orphan</b>		
AZEDRA (iobenguane I 131) 555 MBq/mL injection	Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy	Approved in U.S. July 30, 2018
<b>Prostate Cancer</b>		
I-131-1095	Iodine-131 PSMA-targeted small molecule therapeutic for treatment of metastatic prostate cancer	Announced plans for start of Phase 2 trial Topline data on Phase 2/3 trial released; Phase 3 trial in biochemical recurrence (BCR) patients to begin by year end
PyL	Flourine-18 PSMA-targeted PET/CT imaging agent for prostate cancer	Phase 3 top-line data released; no further investment planned
1404	Technetium-99m PSMA-targeted SPECT/CT imaging agent for prostate cancer	Preclinical development in progress; Phase 1 trial to begin by year end
PSMA TTC (Targeted Thorium Conjugate) [antibody licensed to Bayer]	Thorium-227 PSMA-targeted antibody conjugate therapeutic for treatment of metastatic prostate cancer	Development in progress based on 1404 and PyL data
PSMA AI	Automated reading of PSMA PET/SPECT/CT images based on artificial intelligence (AI) and deep learning	Sold in Japan
automated Bone Scan Index ("aBSI") [licensed to Fuji]	Automated reading of PSMA SPECT/PET/CT images based on artificial intelligence (AI) and deep learning	
<b>Opioid-Induced Constipation ("OIC") Treatment</b>		
RELISTOR Subcutaneous Injection [licensed to Valeant]	Treatment of OIC in adults with chronic non-cancer pain and treatment of OIC in advanced-illness adult patients receiving palliative care when laxative therapy has not been sufficient	Sold in the U.S., European Union, and Canada
RELISTOR Tablets [licensed to Valeant]	Treatment of OIC in adults with chronic non-cancer pain	Sold in the U.S.

*Bausch Agreement*

Under our agreement with Bausch, 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 U.S. marketing approval of an oral formulation of RELISTOR in 2016. We are also eligible to receive up to \$200.0 million of commercialization milestone payments upon first achievement of specified U.S. sales targets in any single calendar year. The following table summarizes the commercialization milestones (in thousands):

<b>Calendar Year Net Sales Level</b>	<b>Payment</b>
In excess of \$100 million	\$10,000
In excess of \$150 million	15,000

In excess of \$200 million	20,000
In excess of \$300 million	30,000
In excess of \$750 million	50,000
In excess of \$1 billion	75,000
	<b>\$200,000</b>

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 Bausch 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) Bausch receives from sublicensees outside the U.S.

Bausch has also entered into license and distribution agreements to expand its sales channels outside of the U.S. for RELISTOR.

#### *Bayer Agreement*

Under our April 2016 agreement with a subsidiary of Bayer AG (“Bayer”) granting Bayer exclusive worldwide rights to develop and commercialize products using our PSMA antibody technology, we received an upfront payment of \$4.0 million and milestone payments totaling \$3.0 million and could receive up to an additional \$46.0 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 as well as royalty payments.

Table of Contents**Results of Operations**

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

	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2018</b>	<b>2017</b>	<b>Change</b>	<b>2018</b>	<b>2017</b>	<b>Change</b>
Total revenue	\$5,317	\$2,697	97%	\$12,384	\$7,809	59%
Operating expenses	\$30,365	\$17,002	(79%)	\$64,188	\$52,927	(21%)
Operating loss	\$(25,048)	\$(14,305)	(75%)	\$(51,804)	\$(45,118)	(15%)
Net loss	\$(24,357)	\$(15,352)	(59%)	\$(52,953)	\$(48,348)	(10%)

**Revenue**

Our sources of revenue include royalties and license fees from Bausch 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):

	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
<b>Source</b>	<b>2018</b>	<b>2017</b>	<b>Change</b>	<b>2018</b>	<b>2017</b>	<b>Change</b>
Royalty income	\$5,169	\$2,562	102%	\$11,757	\$7,282	61%
Other revenue	148	135	10%	627	527	19%
<b>Total revenue</b>	<b>\$5,317</b>	<b>\$2,697</b>	<b>97%</b>	<b>\$12,384</b>	<b>\$7,809</b>	<b>59%</b>

*Royalty income.* We recognized royalty income based on the below net sales of RELISTOR as reported to us by Bausch (in thousands). Bausch reported net sales for the three and nine months ended September 30, 2018 include a non-recurring favorable sales return adjustment.

	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2018</b>	<b>2017</b>	<b>Change</b>	<b>2018</b>	<b>2017</b>	<b>Change</b>
U.S.	\$32,400	\$16,900	92%	\$76,200	\$46,700	63%

Outside U.S.	2,100	200	950%	2,200	1,800	22%
<b>Worldwide net sales of RELISTOR</b>	<b>\$34,500</b>	<b>\$17,100</b>	<b>102%</b>	<b>\$78,400</b>	<b>\$48,500</b>	<b>62%</b>

Royalty income increased by \$2.6 million, or 102%, during the three months ended September 30, 2018, compared to the same period in 2017, and by \$4.5 million, or 61% during the nine months ended September 30, 2018, compared to the same period in 2017, due primarily to higher net sales.

## 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,		
	2018	2017	Change	2018	2017	Change
<b>Operating Expenses</b>						
Research and development	\$8,090	\$10,344	22%	\$25,547	\$31,641	19%
Selling, general and administrative	7,075	5,958	(19%)	21,341	17,986	(19%)
Intangible impairment charge	23,200	-	N/A	23,200	-	N/A
Change in contingent consideration liability	(8,000 )	700	1243%	(5,900 )	3,300	279%
<b>Total operating expenses</b>	<b>\$30,365</b>	<b>\$17,002</b>	<b>(79%)</b>	<b>\$64,188</b>	<b>\$52,927</b>	<b>(21%)</b>

### *Research and Development ("R&D")*

R&D expenses decreased by \$2.3 million, or 22%, during the three months ended September 30, 2018, compared to the same period in 2017. R&D expenses decreased by \$6.1 million, or 19%, during the nine months ended September 30, 2018, compared to the same period in 2017. These decreases were primarily attributable to lower external costs associated with the completion of the Phase 2 study for AZEDRA and the Phase 3 trial for 1404.

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### *Selling, General and Administrative (“SG&A”)*

SG&A expenses increased by \$1.1 million, or 19%, during the three months ended September 30, 2018, compared to the same period in 2017. SG&A expenses increased by \$3.4 million, or 19%, during the nine months ended September 30, 2018, compared to the same period in 2017. These increases were primarily attributable to higher costs associated with the commercial launch of AZEDRA.

### *Intangible Impairment Charge*

The completion of the 1404 Phase 3 trial, whereby only one of the co-primary endpoints was met, negatively impacted our third quarter 2018 assumptions of potential future sales projections, resulting in a \$23.2 million impairment of the 1404 indefinite-lived asset fair value. The corresponding non-cash impairment charge was recorded as part of operating expenses in the condensed consolidated statements of operations.

### *Change in Contingent Consideration Liability*

The decrease in the contingent consideration liability of \$8.0 million and \$5.9 million during the three and nine months ended September 30, 2018, respectively, was primarily attributable to a decrease in sales projections and probability of success for 1404, following results from the recently completed Phase 3 trial, whereby only one of the co-primary endpoints was met, partially offset by higher estimated probability of success of AZEDRA and a decrease in the discount period used to calculate the potential milestone payments to former Molecular Insight stockholders. The increase of \$0.7 million and \$3.3 million during the three and nine months ended September 30, 2017, respectively, resulted primarily from decreases in the discount period used to calculate the present value of the contingent consideration liability and a higher estimated probability of success of AZEDRA used to calculate the potential milestone payments.

### **Other (Expense) Income**

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

<b>Three Months Ended</b>	<b>Nine Months Ended</b>
-------------------------------	------------------------------

	September 30,			September 30,		
	2018	2017	Change	2018	2017	Change
Interest (expense) income, net	\$(670)	\$(985 )	32%	\$(2,469)	\$(3,045)	19%
Other expense, net	(92 )	(62 )	(48%)	(229 )	(185 )	(24%)
<b>Other (expense) income, net</b>	<b>\$(762)</b>	<b>\$(1,047)</b>	<b>27%</b>	<b>\$(2,698)</b>	<b>\$(3,230)</b>	<b>16%</b>

Total other (expense) income, net decreased by \$0.3 million, or 27%, and \$0.5 million, or 16%, during the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017.

### Income Tax Benefit

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
<b>Income tax benefit</b>	<b>\$1,453</b>	<b>\$ -</b>	<b>N/A</b>	<b>\$1,549</b>	<b>\$ -</b>	<b>N/A</b>

We account for income taxes using the liability method in accordance with ASC 740 (Topic 740, *Income Taxes*). Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Income tax expense or benefit related to items not characterized as ordinary income or expense is recognized as a discrete item when incurred.

During the three and nine months ended September 30, 2018, we reduced our deferred tax liability and recorded income tax benefit of \$1.5 million, primarily related to the impairment of an indefinite-lived intangible asset.



Table of Contents**Liquidity and Capital Resources**

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

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
Cash and cash equivalents	\$ 148,851	\$ 90,642
Accounts receivable, net	\$ 5,821	\$ 3,972
Total assets	\$ 182,382	\$ 145,957
Working capital	\$ 140,414	\$ 81,511

Our current principal sources of revenue from operations are royalties and development and commercial milestones. Our principal sources of liquidity are our existing cash and cash equivalents. As of September 30, 2018, we had cash and cash equivalents of approximately \$148.9 million, an increase of \$58.2 million from \$90.6 million at December 31, 2017. We will continue to have significant cash requirements to support product development activities and the commercial launch of AZEDRA. The amount and timing of our cash requirements will depend on the progress and success of our clinical development programs, regulatory and market acceptance, and the resources we devote to research and commercialization activities. The amount of cash on-hand will depend on the progress of various clinical programs, potential sales from the launch of AZEDRA, and the achievement of various milestones and royalties under our existing license agreements.

We believe that our current cash and cash equivalents, which includes \$104.7 million of net proceeds received through September 30, 2018 from an underwritten public offering and the sale of our stock in at-the-market (“ATM”) transactions under a controlled equity offering sales agreement (see *Shelf Registration* section below for additional details), will be sufficient to fund our operations for at least the next twelve months. We expect to fund our operations going forward with existing cash resources, anticipated revenues from our existing license agreements, sales of AZEDRA, and cash that we may raise through future capital raising and other financing transactions.

If we do not realize sufficient royalty or milestone revenue from our license agreements, sales of AZEDRA, or are unable to enter into favorable collaboration, license, asset sale, additional capital raising, or other financing transactions, we will have to reduce, delay, or eliminate spending on certain programs, and/or take other economic measures.

*Shelf Registration*

During the first quarter of 2017, we filed a shelf registration statement on Form S-3 (File No. 333-215454) that permitted: (a) the offering, issuance and sale of up to a maximum aggregate offering price of \$250 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the \$250 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75 million of our common stock under our sales agreement with Cantor Fitzgerald & Co. ("Cantor") in one or more ATM offerings. During the third quarter of 2018, we raised \$70 million, net of underwriting discounts and commissions and offering expenses, in an underwritten public offering of 9.1 million shares of common stock at a public offering price of \$8.25 per share. Through September 30, 2018, we sold a total of approximately 5.1 million shares of our common stock in ATM offerings under the sales agreement, for net proceeds, after deducting commissions and other transaction costs, of approximately \$34.7 million. During the third quarter of 2018, we sold a total of 0.6 million shares of our common stock in ATM transactions under the sales agreement for net proceeds, after deducting commissions and other transaction costs, of approximately \$4.8 million at an average selling price of \$8.36 per share.

On October 12, 2018, we filed a new shelf registration statement on Form S-3 (File No. 333-227805), which was declared effective by the SEC on October 24, 2018. The new shelf registration replaced our prior shelf registration statement, pursuant to which no additional securities will be offered or sold. The new shelf registration statement permits: (a) the offering, issuance and sale of up to a maximum aggregate offering price of \$250 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the \$250 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75 million of our common stock under our sales agreement with Cantor in one or more ATM offerings.

In addition, in October 2018 we entered into a new sales agreement with Cantor, as sales agent, which replaced the previous sales agreement from January 2017. Pursuant to the new sales agreement, we may offer and sell through Cantor, from time to time, shares of our common stock up to an aggregate offering price of \$75 million. This Sales Agreement may be terminated by Cantor or us at any time upon ten (10) days' notice, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in our business or financial condition.

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*Cash Flows*

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

	<b>Nine Months Ended September 30, 2018      2017</b>	
Net cash used in operating activities	\$(37,842)	\$(40,984)
Net cash used in investing activities	\$(595 )	\$(226 )
Net cash provided by financing activities	\$96,739	\$491

*Operating Activities*

Net cash used in operating activities during the nine months ended September 30, 2018 was primarily attributable to operating expenses, net of non-cash items including the intangible impairment charge and change in fair value of contingent consideration liability.

*Investing Activities*

Net cash used in investing activities during the nine months ended September 30, 2018 was primarily related to capital expenditures.

*Financing Activities*

Net cash provided by financing activities during the nine months ended September 30, 2018 was primarily attributable to net proceeds from the sale of our common stock in an underwritten public offering, ATM transactions and 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, 2017. 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 nine months ended September 30, 2018 as noted 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, 2017.

### **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.

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**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Our primary investment objective is to preserve principal. Our money market funds have variable interest rates and totaled \$145.5 million at September 30, 2018. 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 condensed consolidated results of operations, and during the three and nine months ended September 30, 2018 and 2017, 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.

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**

There have been no 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, 2017. 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 8. Commitments and Contingencies* to the accompanying unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

### **Item 1A. Risk Factors**

There have been no material changes from the information discussed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2017, except for the risk factors provided below. You should carefully consider the risks and uncertainties we discussed in our Annual Report and 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 occur, our business, financial condition, operating results, or liquidity could be materially harmed.

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***We may not be able to maintain Orphan Drug exclusivity for AZEDRA and, even if we do, that exclusivity may not prevent the FDA, from approving competing products.***

Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. AZEDRA currently has the Orphan Drug designation in the United States.

In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has Orphan Drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity.

We may not be able to maintain Orphan Drug exclusivity for AZEDRA. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. A loss of the Orphan Drug exclusivity for AZEDRA may have an adverse impact on our ability to adequately commercialize AZEDRA.

***Failure to obtain marketing approval in foreign jurisdictions would prevent AZEDRA from being marketed abroad.***

Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. In order to market and sell AZEDRA in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our

potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize AZEDRA in any market outside of the United States.

***Our AZEDRA commercialization program exposes us to significant risk.***

It is very difficult to estimate the commercial potential of product candidates, due to factors such as safety and efficacy compared to other available treatments (including potential generic drug alternatives with similar efficacy profiles), changing standards of care, third party payer reimbursement, patient and physician preferences and the availability of competitive alternatives that may emerge either during the approval process or after commercial introduction. Frequently, products that have shown promising results in clinical trials suffer significant setbacks even after they are approved for commercial sale.

On July 30, 2018, we received FDA approval of our NDA for AZEDRA. There is no guarantee that AZEDRA will be a commercial success. Further, future uses of AZEDRA commercially may reveal that AZEDRA is ineffective, unacceptably toxic, has other undesirable side effects, is difficult to manufacture on a commercial scale, is not cost-effective or economically viable, infringes on proprietary rights of another party or is otherwise not fit for further use.

AZEDRA, designated as an Orphan Drug is intended to treat a rare disease with a small patient population. While we have received FDA approval, we are still in discussions with payors regarding reimbursement for AZEDRA. If pricing for AZEDRA is not approved or accepted in the market at an appropriate level it may not generate enough revenue to make it economically viable. There have been recent examples of the market reacting poorly to the high cost of certain drugs. If the market reacts similarly to AZEDRA, it could result in negative publicity and reputational harm to us. Further, the Trump administration has indicated support for possible new measures related to drug pricing, which could increase the pricing pressures related to AZEDRA and further limit its economic viability.

We are commercializing AZEDRA in the U.S. through the establishment of a small sales force. We have little experience as a company in commercializing products and prior to FDA approval of AZEDRA, had no existing commercial infrastructure. Given this lack of experience, there is a heightened risk as to whether we will be able to successfully commercialize AZEDRA. If AZEDRA is determined to be unsafe or ineffective in humans, not economically viable or we are unable to successfully commercialize it, our business will be materially adversely affected.



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**Item 6. Exhibits**

(a) Exhibits

**Exhibit**

**Number Description**

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3.1 <sup>(1)</sup>	<u>Amended and Restated Certificate of Incorporation of the Registrant.</u>
3.2 <sup>(2)</sup>	<u>Amended and Restated By-laws of the Registrant.</u>
4.1 <sup>(3)</sup>	<u>Specimen Certificate for Common Stock, \$0.0013 par value per share, of the Registrant.</u>
10.1 <sup>(4)</sup>	<u>Progenics Pharmaceuticals, Inc. 2018 Performance Incentive Plan.</u>
10.2 <sup>(5)</sup>	<u>Settlement and License Agreement by and among Progenics Pharmaceuticals, Inc., Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Wyeth LLC, and Actavis LLC, entered into as of May 25, 2018.</u>
10.3 <sup>(6)</sup>	<u>Settlement and License Agreement by and among Progenics Pharmaceuticals, Inc., Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Wyeth LLC, and Par Sterile Products, LLC and Par Pharmaceutical, Inc., dated May 10, 2018.</u>
10.4 <sup>(7)</sup>	<u>Underwriting Agreement, dated as of August 7, 2018, by and among Progenics Pharmaceuticals, Inc. and Jefferies LLC and Credit Suisse (USA) LLC, as representatives of the several underwriters named in Schedule A thereto.</u>
31.1	<u>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.</u>
31.2	<u>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.</u>
32	<u>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.</u>
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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\* Exhibits footnoted as previously filed have been filed as an exhibit to the document of the Registrant or other registrant referenced in the footnote below, and are incorporated by reference herein.

- (1) Previously filed in Current Report on Form 8-K filed on June 13, 2013.
- (2) Previously filed in Current Report on Form 8-K filed on January 30, 2017.
- (3) Previously filed in Registration Statement on Form S-1, Commission File No. 333-13627.
- (4) Previously filed in Current Report on Form 8-K filed on June 14, 2018.
- (5) Previously filed in Current Report on Form 8-K filed on May 31, 2018.
- (6) Previously filed in Current Report on Form 8-K filed on May 11, 2018.
- (7) Previously filed in Current Report on Form 8-K filed on August 10, 2018.

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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 8, 2018 By: **/s/ Patrick Fabbio**

Patrick Fabbio

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)