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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 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

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0013 per share	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	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 ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant on June 30, 2018, based upon the closing price of the Common Stock on The Nasdaq Stock Market LLC on that date of $8.04 per share, was $380,418,164 (1).

(1) Calculated by excluding all shares that may be deemed to be beneficially owned by executive officers, directors and five percent stockholders of the registrant, without conceding that any such person is an "affiliate" of the registrant for purposes of the federal securities laws.

As of March 11, 2019, a total of 84,542,514 shares of Common Stock, par value $.0013 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2019 Annual Meeting of Shareholders are hereby incorporated by reference into Part III of this Form 10-K where such portions are referenced.

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PART I

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. In evaluating such statements, we urge you to specifically consider the various risk factors identified under Part I, Item 1A. "Risk Factors", which could cause actual events or results to differ materially from those indicated by forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by such 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; a potential inability to obtain sufficient capital, recruit and retain employees, enter into favorable collaborations, transactions or other relationships, or the risk that existing or future relationships or transactions may not proceed as planned; the potential for cybersecurity breaches of our systems and information technology; 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.

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.

Item 1. Business

Overview

Progenics Pharmaceuticals, Inc. is a Delaware corporation that was incorporated on December 1, 1986. Progenics Pharmaceuticals, Inc. (and its subsidiaries collectively the "Company," "Progenics", "we", or "us") is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer. Highlights of our recent progress include the approval, launch and manufacturing of AZEDRA®. Our pipeline includes therapeutic agents designed to precisely target cancer (1095 and PSMA TTC), as well as a prostate-specific membrane antigen ("PSMA") targeted imaging agent for prostate cancer (PyL™).

Recent Progress:

- *AZEDRA® Approval.* On July 30, 2018, the 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, which is a registered trademark, is a radiotherapeutic that 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 FDA-approved therapy for this indication. AZEDRA's approved U.S. label and full U.S. prescribing information is available at www.AZEDRA.com.
- *AZEDRA® Launch.* AZEDRA was launched on 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 five drug compendia: Clinical Pharmacology©; DRUGDEX®; Lexi-Drugs®; NCCN®; and AHFS-DI. 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. Recently we presented data to the CMS ICD-10 Coordination and Maintenance Committee to garner a code associated with AZEDRA which supports our efforts to secure New Technology Add-On Payment (NTAP). In addition, our pass-through C code was approved and is in place, and we anticipate that our permanent A code will be awarded soon. 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. As a result of this effort, treatment requests have been received and sites are now ready to administer AZEDRA. Patient scheduling is underway; however, no commercial sales have been generated as of the date of this filing.
- *AZEDRA® Manufacturing.* In February 2019, we acquired the AZEDRA manufacturing assets for $8.0 million cash consideration and entered into a sublease agreement for the radiopharmaceutical manufacturing facility located in Somerset, New Jersey. The Somerset site serves as the launch facility for AZEDRA and will also provide manufacturing support for our development stage radiopharmaceuticals, including 1095. We also secured the long-term supply of iodine necessary for the production of both AZEDRA and 1095. The production of AZEDRA uses a proprietary Ultratrace® process which concentrates the MIBG targeted radiolytic activity by eliminating non-therapeutic "cold" MIBG molecules, giving AZEDRA a uniquely high specific activity.

Pipeline Advancement:

- We advanced our 1095 program and plan to initiate a Phase 2 trial in the second quarter of 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 trial of PyL which demonstrated its potential high clinical utility. These results were used to design the pivotal Phase 3 trial.
- We commenced a pivotal multi-center, open label Phase 3 trial evaluating the diagnostic performance and clinical impact of PyL in men with biochemical recurrence of prostate cancer. The primary endpoint is based on positive predictive value and will assess the correct localization rate ("CLR"). We expect enrollment to complete by year end 2019.

- Using our PSMA-targeted imaging data from previous trials, we completed a prospectively planned retrospective analysis using our deep convolutional neural network algorithms ("PSMA AI") to automatically assess the PSMA images. The reads with PSMA AI demonstrated a statistically significant improvement over manual assessment in terms of increased diagnostic accuracy, precision, speed, and reproducibility. The results from this analysis are expected to be presented at upcoming scientific conferences.
- We continue to pursue our life cycle management plans for AZEDRA. In February 2019, an advisory board with KOLS concluded that there would likely be strong interest in using AZEDRA in multiple MIBG-avid tumors, including gastroenteropancreatic ("GEP-NETS") and other neuroendocrine tumors ("NETS"). There was strong interest in advancing a basket trial in these indications since patients often have very high unmet needs for new treatments.

PSMA-617:

- *Company Asserts Ownership of PSMA-617 Intellectual Property including Composition of Matter*

  We have commenced a lawsuit disputing the ownership of certain worldwide composition of matter patent filings related to PSMA-617, a PSMA-targeted radiopharmaceutical compound under development by Novartis AG for the treatment of prostate cancer. *See Item 3. Legal Proceedings*

Product / Candidate	Description	Status	Market	Rights
Ultra-Orphan Theranostic				
AZEDRA (iobenguane I 131) 555 MBq/mL injection	Unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma	Approved	U.S	Proprietary
Prostate Cancer Theranostics				
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	Phase 3	U.S. & Canada	Proprietary
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	Meeting with EMA	Europe	Curium
1095 (I 131 1095)	PSMA-targeted small molecule therapeutic for treatment of metastatic prostate cancer	Phase 2	Worldwide	Proprietary
PSMA-TTC (BAY 2315497)	PSMA-targeted antibody conjugate therapeutic for treatment of metastatic prostate cancer	Phase 1	Worldwide	Bayer
Digital Technology				
PSMA AI	Imaging analysis technology that uses artificial intelligence and machine learning to quantify and automate the reading of PSMA targeted imaging	Investigational Use Only	Worldwide	Proprietary
Automated Bone Scan Index (aBSI)	Automated reading and quantification of bone scans of prostate cancer patients using artificial intelligence and deep learning	CE MARK (EU countries) Investigational Use Only (USA)	Worldwide (ex. Japan)	Proprietary
Automated Bone Scan Index (BONENAVI)	Automated reading and quantification of bone scans of prostate cancer patients using artificial intelligence and deep learning	Approved	Japan	Fuji
Other Programs				
RELISTOR Subcutaneous Injection (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain or advanced-illness adult patients	Approved	U.S. & Canada	Bausch
RELISTOR Tablets (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain	Approved	U.S.	Bausch
Leronlimab (PRO 140)	HIV Infection	Phase 3	U.S.	CytoDyn

Ultra-Orphan Theranostic:

- **AZEDRA** is a radiotherapeutic, approved 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 FDA-approved therapy for this indication. We anticipate opportunities for growth of AZEDRA through the development of new indications in 2019.

Prostate Cancer Theranostics:

- **PyL™ (also known as 18F-DCFPyL)** is a fluorinated PSMA-targeted PET imaging agent that enables visualization of both bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer. In the US, we are conducting a pivotal Phase 3 trial evaluating the diagnostic performance and clinical impact of PyL in men with biochemical recurrence of prostate cancer. Curium has licensed exclusive rights to develop and commercialize PyL in Europe. Curium plans to meet with the EMA to agree upon the regulatory path forward for PyL in 2019.

- **1095 (also known as I-131-1095)** is a PSMA-targeted Iodine-131 labeled small molecule that is designed to deliver a dose of beta radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. In October 2018, we announced plans to advance I-131 1095, its PSMA-targeted therapeutic, into a Phase 2 clinical trial in the second quarter of 2019.
- **PSMA TTC** is a thorium-227 labeled PSMA-targeted antibody therapeutic. PSMA-TTC is designed to deliver a dose of alpha radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. 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. Bayer initiated a Phase 1 trial of PSMA TTC in patients with metastatic castration-resistant prostate cancer.

Digital Technology:

- **PSMA AI** is an imaging analysis technology that uses artificial intelligence and machine learning to quantify and automate the reading of PSMA-targeted imaging. We recently completed a prospectively planned retrospective analysis using our deep convolutional neural network algorithms to automatically assess a set of the PSMA images from prior trials. The results from this analysis are expected to be presented at upcoming scientific conferences.
- **Automated Bone Scan Index (aBSI)** calculates the disease burden of prostate cancer by quantifying the hotspots on bone scans and automatically calculating the bone scan index value, representing the disease burden of prostate cancer shown on the bone scan. This quantifiable and reproducible calculation of the bone scan index value is intended to aid in the diagnosis and treatment of men with prostate cancer and may have utility in monitoring the course of the disease. aBSI is licensed as a standalone software to FUJIFILM RI Pharma Co., Ltd. ("Fuji") in Japan and is sold under the name BONENAVI®. aBSI is also available as a cloud-based software for research only purposes with the United States.

Other Programs:

- **RELISTOR** is a treatment for opioid-induced constipation ("OIC") that addresses its underlying mechanism of OIC and decreases the constipating side effects induced by opioid pain medications such as morphine and codeine without diminishing their ability to relieve pain. RELISTOR is approved in two forms a subcutaneous injection (12 mg and 8 mg) and an oral tablet (450 mg once daily). Any references herein to RELISTOR do not imply that any other form or possible use of the drug has received approval. RELISTOR subcutaneous injection is being sold in the U.S., European Union ("E.U."), and Canada, and RELISTOR tablets are being sold in the U.S. RELISTOR's approved U.S. label and full U.S. prescribing information is available at www.RELISTOR.com. Other approved labels for RELISTOR apply in ex-U.S. markets. Our recognition of royalty income for financial reporting purposes is explained in *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* and our consolidated financial statements included elsewhere in this document.
- **Leronlimab (PRO 140)** is a fully humanized monoclonal antibody which is a cellular targeting CCR5 entry antagonist and is currently in Phase 3 development for the treatment of HIV infection. It is owned by CytoDyn and, pursuant to our agreement with CytoDyn, we have the right to receive certain milestone and royalty payments. CytoDyn has announced plans to submit on a rolling basis its biologics license application ("BLA") to the FDA during 2019.

We may consider opportunities to out-license our development and clinical programs. We may also in-license or acquire additional oncology compounds and/or programs.

Clinical Trial Activities

For purposes of this report, in general Phase 1 trials are initial evaluations of safety in humans which study mechanism of action and metabolism; Phase 2 trials evaluate safety, dosing and activity or efficacy, and continue safety evaluation; and Phase 3 trials involve larger scale evaluations of safety, efficacy and dosing.

Our practice is and has been to announce commencement and results of all our significant clinical trials in press releases, medical and scientific meetings, and other venues. The following is a summary of current clinical trial activities involving our principal product candidates.

PyL. PyL is a clinical-stage fluorinated PSMA-targeted PET imaging agent for prostate cancer. PyL has shown potential for use in identifying metastatic prostate cancer. We have an exclusive worldwide license (excluding Australia and New Zealand) to develop and commercialize PyL in PET imaging applications.

In October 2018, we announced results of a Phase 2/3 OSPREY trial that assessed the safety and efficacy of PyL in the detection of prostate cancer. In the trial, PyL demonstrated high sensitivity in reliably detecting distant metastatic prostate cancer lesions and high specificity in confirming the absence of pelvic lymph node disease. The associated strong positive predictive values and negative predictive value of PyL imaging in these disease settings indicate its potential high clinical utility.

PyL Phase 2/3 OSPREY Trial - Topline Results

	Cohort A	Cohort B
Objective	Detect prostate cancer in pelvic lymph nodes in patients with high risk locally advanced	Detect prostate cancer in distant metastases in patients with metastatic or recurrent
N	268	117
Specificity	96% - 99%	Not evaluated; Cohort B suspected to have disease
Negative Predictive Value	81% - 84%	Not evaluated; Cohort B suspected to have disease
Sensitivity	31% - 42%	93% - 99%
Positive Predictive Value	78% - 91%	81% - 88%
Trial achieved co-primary endpoint for specificity in Cohort A; did not meet co-primary endpoint for sensitivity in Cohort A. Secondary endpoints included: sensitivity in Cohort B; PPV and NPV in Cohort A; and, PPV in Cohort B.		

Overall, PyL was safe and well-tolerated by all dosed subjects. A total of 81 treatment-emergent adverse events ("TEAEs") were reported in 51 (13.2%) subjects with the most common being fatigue (1.3%), dysgeusia (2.6%), and headache (2.3%). A total of five subjects (1.3%) experienced TEAE(s) that were ≥ Grade 3 in severity; all were Grade 3 and no subjects experienced Grade 4 or 5 adverse events. A total of seven serious adverse events ("SAEs") have been reported within the protocol-specified period in subjects who received PyL. All of the SAEs were assessed as unrelated to the study drug.

In December 2018, we announced the start of a pivotal, Phase 3 CONDOR trial evaluating the diagnostic performance and clinical impact of PyL in men with biochemical recurrence of prostate cancer. The Phase 3 CONDOR trial is a multi-center, open label trial and is expected to enroll approximately 200 patients with biochemical recurrence of prostate cancer in 15 sites in the United States and Canada. The primary endpoint is based on positive predictive value and will assess the correct localization rate (CLR), defined as a percentage of subjects with a one-to-one correspondence between localization of at least one lesion identified by PyL and the composite truth standard. Secondary measures include the percentage of subjects with a change in intended prostate cancer treatment plans due to PyL PET/CT imaging.

In addition to our sponsored studies and clinical trial collaborations we anticipate that PyL's potential activity will also be explored in investigator sponsored studies at various academic institutions.

1404. We conducted five Phase 1 trials with 1404 in healthy volunteers as well as men with prostate cancer, to establish proof-of-concept and dosimetry, and to assess a simplified kit preparation as compared to multi-step preparation. We then conducted a Phase 2 trial in the U.S. and Europe to assess the safety and ability of 1404 to detect prostate cancer within the prostate gland. Analysis of 1404 SPECT/CT images from this study showed that uptake of 1404 in the lobes of the prostate gland correlated significantly with Gleason score ($p<0.0001$). No deaths, serious adverse events, or adverse events leading to discontinuations occurred during the study. Of the 105 subjects who received a 1404 injection, four subjects reported a total of ten TEAEs with one related to 1404 (infusion site extravasation). No discernible trends in hematology, clinical chemistries, vital signs, or physical findings were observed during the study.

Based on results from these studies, a multi-center, open-label Phase 3 trial was initiated in December 2015 to evaluate the (i) specificity of 1404 to detect clinically insignificant prostate cancer and (ii) sensitivity of 1404 to detect clinically significant disease in patients with newly-diagnosed or low-grade prostate cancer, whose biopsy indicates a histopathologic Gleason grade of ≤3+4 severity and/or were candidates for active surveillance. In December 2017, we completed enrollment (N=471) in the Phase 3 trial. Median PSA levels for patients dosed in trial was 5.58 ng/mL (range 0.69 – 16.03). In the study, 1404 detected clinically meaningful prostate cancer with specificity ranging among the three readers from 71-75% (95% confidence interval CI of 64% to 80%). The co-primary endpoint of sensitivity was not met and ranged amongst the three readers from 47-51% (95% CI of 41% to 56%). The trial protocol required the lower limit of the two-sided 95% CI for both specificity and sensitivity to exceed 60%. The most frequent treatment related events included headache (2.3%), dizziness (1.1%) and fatigue (0.8%). In November 2018, 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 not to further invest in 1404.

1095. In October 2018, we announced plans to initiate a multicenter, randomized, controlled Phase 2 trial that 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.

The 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. 1095 radiotherapy represents a new mechanism of action that may overcome resistance developed to novel androgen axis drugs (NAADs), such as abiraterone and enzalutamide. In addition, recent preclinical research reported that enzalutamide can sensitize cells to radiotherapy induced cell death, suggesting that 1095 in combination with enzalutamide has the potential to be an effective treatment paradigm for patients with mCRPC who are resistant to NAADs.

The study's primary endpoint will be prostate specific antigen (PSA) response rate according to Prostate Cancer Clinical Trials Working Group 3 (PCWG3) criteria defined as a confirmed 50% or greater decline from baseline of 1095 and enzalutamide compared to enzalutamide alone. Secondary endpoints will evaluate radiographic response based on Response Evaluation Criteria In Solid Tumors (RECIST), Progression Free Survival (PFS) and overall survival (OS). Tumor avidity will be determined utilizing PyL, the Company's PET imaging agent designed to visualize prostate cancer.

License Agreements and Other Arrangements

Molecular Insight Pharmaceuticals, Inc. License Agreements

In January 2013, we acquired Molecular Insight Pharmaceuticals, Inc. ("MIP") by purchasing all of its outstanding capital stock for 4.5 million shares of our common stock in a private transaction. Under the agreement, we also agreed to pay to the former stockholders potential milestones, in cash or our stock at our option, of up to $23.0 million contingent upon achieving specified commercialization events ($8.0 million for the first commercial sale of AZEDRA, which has not occurred) and up to $70.0 million contingent upon achieving specified sales targets relating to the acquired company's products. The timing of any such payments, if any, remains uncertain.

In addition to utilizing our own proprietary technology, we have a number of agreements with owners of intellectual property which we use or believe may be useful in the research, development and commercialization of product candidates, including:

- A 2012 co-exclusive license agreement with the University of Zurich and the Paul Scherrer Institute for worldwide sublicensable rights to certain intellectual property related to production methodologies relevant to 1404. Under this agreement, we maintain related patent rights and are obligated to pay low single-digit royalties on products using the licensed technology, license maintenance fees creditable against royalties, an annual fee for an option to expand the license's field of use, and clinical and regulatory milestone payments aggregating to approximately $1.8 million. The agreement may be terminated by the licensors upon certain material defaults by, and automatically terminates upon certain bankruptcy events relating to MIP and may be terminated by us on prior written notice.

- A 2012 out-license agreement with Fuji for the development and commercialization of 1404 in Japan. Under this agreement, we received upfront and milestone payments, of $3.0 million and $1.0 million, respectively, and we have the right to receive additional potential future milestone and royalty payments.

- The 2000 and 2003 exclusive license agreements with The University of Western Ontario for worldwide sublicensable rights to certain intellectual property related to production methodologies relevant to AZEDRA. The 2000 agreement terminated in 2018 with the expiration of the patents associated with the agreement. The 2003 agreement for the license of patent families related to alternative approaches for preparing AZEDRA continues to be in effect. This alternative technology has not been implemented. Under the 2003 agreement, we maintain related patent rights and are obligated to pay low single-digit royalties on products using the licensed technology, minimum annual royalties creditable against royalties and clinical and regulatory milestone payments aggregating to approximately $0.3 million.

We have also entered into a number of in-license and out-license agreements, such as:

In-License Agreement

- An August 2015 agreement with Johns Hopkins University ("JHU"), granting us exclusive worldwide rights (with the exception of Australia and New Zealand) for PyL. Under this agreement, we are obligated to pay milestone payments, low single-digit royalties, patent costs and minimum annual royalties which are creditable against royalties, aggregating to approximately $2.9 million.

Out-License Agreements

- An 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, in combination with Bayer's alpha-emitting radionuclides. Bayer is developing PSMA TTC, a thorium-227 labeled PSMA-targeted antibody therapeutic. Bayer initiated a Phase 1 trial of PSMA TTC in patients with metastatic castration-resistant prostate cancer. Pursuant to the agreement, 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 development milestones. We are also entitled to single-digit royalties on net sales, and potential net sales milestone payments up to an aggregate of $130.0 million.

- A December 2018 agreement with Curium, granting Curium exclusive sublicense to develop, manufacture and commercialize PyL™ (18F-DCFPyL) in Europe. Curium will be responsible for the development, regulatory approvals and commercialization of PyL in Europe. We understand from Curium that it plans to meet with the European Medicines Agency to agree upon the regulatory path forward for PyL in 2019. Under this agreement, we are entitled to double-digit royalties on net sales of PyL.

RELISTOR License Agreement

RELISTOR® is a registered trademark and refers to methylnaltrexone – the active ingredient of RELISTOR – as it has been and is being developed and commercialized by or in collaboration with Salix Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Bausch Health Companies Inc. ("Bausch", which is the predecessor of Valeant Pharmaceuticals International, Inc.), under a license agreement (the "RELISTOR License Agreement"). Under the RELISTOR License Agreement, Bausch is responsible for developing and commercializing RELISTOR worldwide, including completing clinical development necessary to support regulatory marketing approvals for potential new indications and formulations, and marketing and selling the product. Bausch is marketing RELISTOR directly through its specialty sales force in the U.S., and outside the U.S. directly through distribution and marketing partners. Under the RELISTOR License Agreement, we recognized a development milestone payment of $40.0 million upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients in 2014, and a development milestone payment of $50.0 million for the U.S. marketing approval of an oral formulation of RELISTOR in July 2016. We are also eligible to receive up to $200.0 million of commercialization milestone payments upon achievement of specified U.S. net sales targets, including:

U.S. Net Sales Level in any Single Calendar Year	Payment (In thousands)
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
	$ 200,000

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 $100.0 million, 17% on the next $400.0 million in worldwide net sales, and 19% on worldwide net sales over $500.0 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.

The RELISTOR License Agreement may be terminated by either party upon an uncured material breach or specified bankruptcy events. In addition, Bausch may terminate the RELISTOR License Agreement for unresolved safety or efficacy issues or at its discretion upon specified prior notice at any time, subject to our one-time right to postpone such termination for a specified period of time if we have not successfully transitioned the development and commercialization of the drug despite good faith and diligent efforts. See *Item 1A. Risk Factors.*

We have licensed to Bausch our exclusive rights to develop and commercialize methylnaltrexone, the active ingredient of RELISTOR, which we in-licensed from the University of Chicago ("UC"). Our agreement with UC provides for an exclusive license to intellectual property in exchange for development and potential commercialization obligations, low single-digit royalties on commercial sales of resulting products and single-digit percentages of milestone and sublicensing revenues, and shared patent policing responsibilities. Under the UC agreement, as amended in connection with our RELISTOR collaborations, all of our royalty payment obligations expired at the end of 2017 in the U.S. and expired at the end of 2018 outside the U.S. on the approved indications.

Bausch has also entered into license and distribution agreements to expand its sales channels outside of the U.S. for RELISTOR. In January 2016, Bausch entered into a distribution agreement with Swedish Orphan Biovitrum AB, also known as Sobi, for RELISTOR in Western Europe, Russia and Greece. In 2016, we recognized license revenue of $720 thousand for our share of the upfront payment Bausch received from Lupin Limited pursuant to a distribution agreement for RELISTOR in Canada.

CytoDyn Agreement

We sold Leronlimab (PRO 140) to CytoDyn Inc. ("CytoDyn") in 2012, which sale included milestone and royalty payment obligations to us. Leronlimab is a fully humanized monoclonal antibody which is a cellular targeting CCR5 entry antagonist and is currently in development for the treatment of HIV. CytoDyn has announced plans to submit on a rolling basis its BLA to the FDA during 2019.

Under our 2012 agreement with CytoDyn, CytoDyn is responsible for all development, manufacturing and commercialization efforts. Pursuant to such agreement, we have received $5.0 million in upfront and milestone payments, together with rights to receive an additional $5.0 million upon the first U.S. or E.U. approval for the sale of the drug, and a 5% royalty on the net sales of approved product(s).

Patents and Proprietary Technology

Protection of our intellectual property rights is important to our business. We seek U.S. patent protection for many of our inventions, and generally file patent applications in Canada, Japan, European countries that are party to the European Patent Convention, and other countries on a selective basis in order to protect inventions we consider to be important to the development of business in those areas. Generally, patents issued in the U.S. are effective for either (i) 20 years from the earliest asserted filing date, if the application was filed on or after June 8, 1995, or (ii) the longer of 17 years from the date of issue or 20 years from the earliest asserted filing date, if the application was filed prior to that date.

In certain instances, the U.S. patent term can be extended up to a maximum of five years to recapture a portion of the term during which FDA regulatory review was being conducted. The duration of foreign patents varies in accordance with the provisions of applicable local law, although most countries provide for patent terms of 20 years from the earliest asserted filing date and allow patent extensions similar to those permitted in the U.S.

Patents may not enable us to preclude competitors from commercializing drugs in direct competition with our products, and consequently may not provide us with any meaningful competitive advantage. See *Item 1A. Risk Factors.* We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position in our product areas. We require our employees, consultants and corporate partners who have access to our proprietary information to sign confidentiality agreements.

Information with respect to our current patent portfolio is set forth below.

The original patents surrounding the AZEDRA program were licensed from the University of Western Ontario ("UWO"). The patent family directed to processes for making polymer precursors, as well as processes for making the final product, expired in 2018 in the U.S. and Canada. The related UWO agreement terminated with the expiration of the patents. Other licensed patent families from UWO under a second agreement relate to alternative approaches for preparing AZEDRA, which if implemented, would expire in 2024 worldwide. We have pending applications worldwide directed to manufacturing improvements and the resulting compositions which, if issued, would expire in 2035.

Owned and in-licensed patents relating to 1404 have expiration ranges of 2020 to 2029; we view as most significant the composition-of-matter patent on the compound, as well as technetium-99 labeled forms, which expire in 2029 worldwide.

The PyL patent family was licensed from Johns Hopkins University. Patent protection for the composition-of-matter patents on the compound, radiolabeled forms of the compound, as well as methods of use, expire in 2030 in the U.S. Corresponding patent family members are pending or issued worldwide, all expiring in 2029. Process improvement patent applications are pending worldwide which, if issued, would expire in 2037.

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

We own patents relating to automated detection of bone cancer metastases. The patents on this technology expire in 2028. The US patent is currently under reexamination. Patent applications are pending relating to automated medical image analysis.

The intellectual property directed to PSMA antibody comprises co-owned patents. Composition-of-matter patents have expirations of 2022 in the U.S. Corresponding foreign counterpart patents will expire 2022. We view all of these patents as significant.

With regard to our RELISTOR-related intellectual property, the composition-of-matter patent for the active ingredient of RELISTOR, methylnaltrexone, has expired. University of Chicago, as well as we and our collaborators, have extended the methylnaltrexone patent estate with additional patents and pending patent applications covering various inventions relating to the product. Bausch has listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") seven U.S. patents relating to subcutaneous RELISTOR, which have expiration dates ranging from 2024 to 2030, and seven U.S. patents relating to RELISTOR tablet, which have expiration dates ranging from 2029 to 2031. Four Canadian patents (expiring in 2024, 2027 and 2029) have been listed with Health Canada relating to subcutaneous RELISTOR.

We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, we are aware of others investigating and developing technologies, imaging agents and drug candidates directed toward PSMA or related compounds as well as in the case of methylnaltrexone, others are developing peripheral opioid antagonists, and of patents and applications held or filed by others in those areas. The validity of issued patents, patentability of claimed inventions in pending applications and applicability of any of them to our programs are uncertain and subject to change, and patent rights asserted against us could adversely affect our ability to commercialize or collaborate with others on specific products.

Research, development, and commercialization of a biopharmaceutical product often require choosing between alternative development and optimization routes at various stages in the development process. Preferred routes depend upon current – and may be affected by subsequent – discoveries and test results and cannot be identified with certainty at the outset. There are numerous third-party patents in fields in which we work, and we may need to obtain license under patents of others in order to pursue a preferred development route of one or more of our product candidates. The need to obtain a license would decrease the ultimate value and profitability of an affected product. If we cannot negotiate such a license, we might have to pursue a less desirable development route or terminate the entire program altogether.

Seasonality

As is typical in the pharmaceutical industry, our business may experience modest seasonality due to patient co-pays and co-insurance being reset at the beginning of the calendar year and patients meeting their deductibles over the course of the calendar year. As a result, demand for our products such as RELISTOR and associated revenue may be lower in the beginning of the year.

Government Regulation

We and our product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries. Pharmaceutical regulation currently is a topic of substantial interest in lawmaking and regulatory bodies in the U.S. and internationally, and numerous proposals exist for changes in FDA and non-U.S. regulation of pre-clinical and clinical testing, approval, safety, effectiveness, manufacturing, storage, recordkeeping, labeling, marketing, export, advertising, promotion and other aspects of biologics, small molecule drugs and medical devices, many of which, if adopted, could significantly alter our business and the current regulatory structure described below. See *Item 1A. Risk Factors.*

FDA Regulation

FDA approval, which involves review of scientific, clinical and commercial data, manufacturing processes and facilities, is required before a product candidate may be marketed in the U.S. This process is costly, time consuming and subject to unanticipated delays, and a drug candidate may fail to progress at any point.

Other than AZEDRA and RELISTOR, none of our product candidates have received marketing approval from the FDA or any other regulatory authority. The process required by the FDA before product candidates may be approved for marketing in the U.S. generally involves:

- pre-clinical laboratory and animal tests;
- submission to and favorable review by the FDA of an investigational new drug application before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication (animal and other nonclinical studies also are typically conducted during each phase of human clinical trials);
- submission to the FDA of a marketing application; and
- FDA review of the marketing application in order to determine, among other things, whether the product is safe and effective for its intended uses.

Pre-clinical tests include laboratory evaluation of product chemistry and animal studies to gain preliminary information about a compound's pharmacology and toxicology and to identify safety problems that would preclude testing in humans. Since product candidates must generally be manufactured according to current Good Manufacturing Practices ("cGMP"), pre-clinical safety tests must be conducted by laboratories that comply with FDA good laboratory practices regulations. Pre-clinical testing is preceded by initial research related to specific molecular targets, synthesis of new chemical entities, assay development and screening for identification and optimization of lead compound(s).

Results of pre-clinical tests are submitted to the FDA as part of an IND, which must become effective before clinical trials may commence. The IND submission must include, among other things, a description of the sponsor's investigational plan; protocols for each planned study; chemistry, manufacturing and control information; pharmacology and toxicology information and a summary of previous human experience with the investigational drug. Unless the FDA objects to, makes comments or raises questions concerning an IND, it becomes effective 30 days following submission, and initial clinical studies may begin. Companies often obtain affirmative FDA approval, however, before beginning such studies.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or to individuals under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice requirements under protocols submitted to the FDA that detail, among other things, the objectives of the trial, parameters used to monitor safety and effectiveness criteria to be evaluated. Each clinical trial must be conducted under the auspices of an Institutional Review Board, which considers, among other things, ethical factors, safety of human subjects, possible liability of the institution and informed consent disclosure which must be made to participants in the trial.

Clinical trials are typically conducted in three sequential phases, which may overlap. During Phase 1, when the drug is initially administered to human subjects, the product is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 2 involves studies in a limited population to evaluate preliminarily the efficacy of the product for specific, targeted indications, determine dosage tolerance and optimal dosage and identify possible adverse effects and safety risks.

When a product candidate is found in Phase 2 evaluation to have an effect and an acceptable safety profile, Phase 3 trials are undertaken in order to further evaluate clinical efficacy and test for safety within an expanded population. Safety studies are conducted in accordance with the FDA's International Conference on Harmonization Guidelines. Phase 2 results do not guarantee a similar outcome in Phase 3 trials. The FDA may suspend clinical trials at any point in this process if it concludes that clinical subjects are being exposed to an unacceptable health risk.

An NDA is an application to the FDA to market a new drug. A BLA is an application to market a biological product. The new drug or biological product may not be marketed in the U.S. until the FDA has approved the NDA or issued a biologics license. The NDA must contain, among other things, information on chemistry, manufacturing and controls; non-clinical pharmacology and toxicology; human pharmacokinetics and bioavailability; and clinical data. The BLA must contain, among other things, data derived from nonclinical laboratory and clinical studies which demonstrate that the product meets prescribed standards of safety, purity and potency, and a full description of manufacturing methods. Supplemental NDAs are submitted to obtain regulatory approval for additional indications for a previously approved drug and are reviewed by the FDA in a similar manner.

The results of the pre-clinical studies and clinical studies, the chemistry and manufacturing data, and the proposed labeling, among other things, are submitted to the FDA in the form of an NDA or BLA. The FDA may refuse to accept the application for filing if certain administrative and content criteria are not satisfied, and even after accepting the application for review, the FDA may require additional testing or information before approval of the application, in either case based upon changes in applicable law or FDA policy during the period of product development and FDA regulatory review. The applicant's analysis of the results of clinical studies is subject to review and interpretation by the FDA, which may differ from the applicant's analysis, and in any event, the FDA must deny an NDA or BLA if applicable regulatory requirements are not ultimately satisfied. If regulatory approval of a product is granted, such approval may be made subject to various conditions, including post-marketing testing and surveillance to monitor the safety of the product, or may entail limitations on the indicated uses for which it may be marketed. Product approvals may also be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

Orphan Drug, Fast Track, Breakthrough Therapy Designations, and Priority Review

Other FDA regulations and policies relating to drug approval have implications for certain of our current or future product candidates, particularly AZEDRA. Designation as an Orphan Drug is available under U.S., E.U., and other laws for drug candidates intended to treat rare diseases or conditions, and which if approved are granted a period of market exclusivity, subject to various conditions. Orphan Drug designation does not shorten or otherwise convey any advantage in the regulatory approval process. Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is intended to treat a rare disease or condition, generally defined as a patient population of fewer than 200,000 in the U.S. AZEDRA is designated as an Orphan Drug.

In the U.S., Orphan Drug designation entitles a party to certain financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan 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.

In cases where the extent and scope of patent protection for a product is limited, the exclusivity period resulting from Orphan Drug designation may be important in helping products maintain a competitive position. Even if a product obtains Orphan Drug exclusivity, however, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an Orphan Drug is approved, the FDA may 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.

The FDA is also authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These mechanisms for expedited review include fast track designation, breakthrough therapy designation and priority review designation. AZEDRA has received fast track, breakthrough therapy and priority review designations.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Finally, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Both before and after approval is obtained, a product, its manufacturer and the sponsor of the marketing application for the product are subject to comprehensive regulatory oversight. Violations of existing or newly-adopted regulatory requirements at any stage, including the pre-clinical and clinical testing process, the approval process, or thereafter, may result in various adverse consequences, including FDA delay in approving or refusal to approve a product, withdrawal of an approved product from the market or the imposition of criminal penalties against the manufacturer or sponsor. Later discovery of previously unknown problems may result in restrictions on the product, manufacturer or sponsor, including withdrawal of the product from the market.

Regulation Outside the U.S.

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable government regulatory authorities abroad must be obtained prior to marketing the product there. The approval procedure varies from country to country, and the time required may be longer or shorter than that required for FDA approval. The requirements for regulatory approval by governmental agencies in other countries prior to commercialization of products there can be rigorous, costly and uncertain, and approvals may not be granted on a timely basis or at all.

In E.U. countries, Canada, Australia, and Japan, regulatory requirements and approval processes are similar in principle to those in the U.S. Regulatory approval in Japan requires that clinical trials of new drugs be conducted in Japanese patients. Depending on the type of drug for which approval is sought, there are currently two potential tracks for marketing approval in E.U. countries: mutual recognition and the centralized procedure. These review mechanisms may ultimately lead to approval in all E.U. countries, but each method grants all participating countries some decision-making authority in product approval. The centralized procedure, which is mandatory for biotechnology derived products, results in a recommendation in all member states, while the E.U. mutual recognition process involves country-by-country approval.

In other countries, regulatory requirements may require additional pre-clinical or clinical testing regardless of whether FDA or European approval has been obtained. This is the case in Japan, where trials are required to involve patient populations which we and our other collaborators have not examined in detail. If a product is manufactured in the U.S., it is also subject to FDA and other U.S. export provisions. In most countries outside the U.S., coverage, pricing and reimbursement approvals are also required, which may affect the profitability of the affected product.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to regulation under the U.S. Occupational Safety and Health Act, Environmental Protection Act, Toxic Substances Control Act, Resource Conservation and Recovery Act, and various other current and potential future U.S. federal, state or local regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations. Our compliance with these regulations during the past year did not have and is not expected to have a material effect upon our capital expenditures, cash flows, earnings or competitive position.

In addition, our research is dependent on maintenance of licenses from various authorities permitting the acquisition, use and storage of quantities of radioactive isotopes that are critical for its manufacture and testing of research products. Biopharmaceutical research and development generally involves the controlled use of hazardous materials, chemicals, viruses, and various radioactive compounds. Even strict compliance with safety procedures for storing, handling, using and disposing of such materials prescribed by applicable regulations cannot completely eliminate the risk of accidental contaminations or injury from these materials, which may result in liability for resulting legal and regulatory violations as well as damages.

Manufacturing

The manufacture of radiopharmaceuticals is complex and requires significant capital expenditures. We have to date engaged third-party contract manufacturing organizations ("CMOs") to manufacture active pharmaceutical ingredient ("API") and finished drug products for clinical trial supplies of all of our product candidates, including AZEDRA, 1404, PyL and 1095. We recently acquired the AZEDRA manufacturing assets and entered into a sublease agreement for the radiopharmaceutical manufacturing facility located in Somerset, New Jersey. The Somerset site serves as the launch facility for AZEDRA and will also provide manufacturing support for our development stage radiopharmaceuticals, including 1095. We continue to depend significantly on the availability of high quality CMO services. If we are unable to arrange for satisfactory CMO services, we would need to undertake such responsibilities on our own, resulting in our having to incur additional expenses and potentially delaying the development of our product candidates. See *Item 1A. Risk Factors*.

Under the RELISTOR License Agreement, Bausch is responsible for the manufacture and supply, at its expense, of all API and finished and packaged products for its RELISTOR commercialization efforts, including contracting with CMOs for supply of RELISTOR API and subcutaneous and oral finished drug product.

Commercial Organization

We have built an experienced radiopharmaceutical team of 13 employees to commercialize AZEDRA in the U.S.

Competition

Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. We face competition from many for-profit companies and major universities and research institutions in the U.S. and abroad. We face competition from companies marketing existing products or developing new products for diseases targeted by our technologies. Many of our competitors have substantially greater resources, experience in conducting pre-clinical studies and clinical trials and obtaining regulatory approvals for their products, operating experience, research and development and marketing capabilities and production capabilities than we do. Our products and product candidates under development may not compete successfully with existing products or products under development by other companies, universities and other institutions. Drug manufacturers that are first in the market with a therapeutic for a specific indication generally obtain and maintain a significant competitive advantage over later entrants and therefore, the speed with which industry participants move to develop products, complete clinical trials, approve processes and commercialize products is an important competitive factor.

RELISTOR was the first FDA-approved product for any indication involving OIC. We are, however, aware of other approved and marketed products, as well as candidates in pre-clinical or clinical development, that target the side effects of opioid pain therapy. Our principal competitors in the field of OIC include Nektar Therapeutics, in collaboration with AstraZeneca PLC; Cubist Pharmaceuticals, a subsidiary of Merck & Co., Inc.; and Mallinckrodt plc, in collaboration with Takeda Pharmaceutical Company Limited; and Shionogi, Inc. Other prescription, as well as over-the-counter, laxatives are also used as first line for OIC.

As to our oncology pipeline, radiation and surgery are two traditional forms of treatment for prostate cancer. If the disease spreads, hormone (androgen) suppression therapy is often used to slow the cancer's progression, but this form of treatment can eventually become ineffective. We are aware of several competitors who are developing or have received approval for treatments for castration-resistant prostate cancer. Our principal competitors in the field of mCRPC include Johnson & Johnson subsidiary Janssen Biotech, Inc.; Novartis AG and Pfizer, Inc. in collaboration with Astellas Pharma US, Inc.; and Bayer HealthCare Pharmaceuticals Inc. Our principal competitors in the field of PSMA-targeted imaging agents include Aytu Bioscience Inc., Blue Earth Diagnostics, Limited and Novartis AG.

Other than AZEDRA, there are currently no approved anticancer treatments in the U.S. for malignant, recurrent, and/or unresectable pheochromocytoma and paraganglioma.

A significant amount of research in the biopharmaceutical field is carried out at academic and government institutions. An element of our research and development strategy has been to in-license technology and product candidates from academic and government institutions. These institutions are sensitive to the commercial value of their findings and pursue patent protection and negotiate licensing arrangements to collect royalties for use of technology they develop. They may also market competitive commercial products on their own or in collaboration with competitors and compete with us in recruiting highly qualified scientific personnel, which may result in increased costs or decreased availability of technology or product candidates from these institutions to other industry participants.

Competition with respect to our technologies and products is based on, among other things, product efficacy, safety, reliability, method of administration, availability, price and clinical benefit relative to cost; timing and scope of regulatory approval; sales, marketing and manufacturing capabilities; collaborator capabilities; insurance and other reimbursement coverage; and patent protection. Competitive position in our industry also depends on a participant's ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes, and secure sufficient capital resources for the typically substantial period between technological conception and commercial sales.

Product Liability

The testing, manufacturing and marketing of our product candidates and products involves an inherent risk of product liability attributable to unwanted and potentially serious health effects. To the extent we elect to test, manufacture or market product candidates and products independently, we bear the risk of product liability directly. We maintain product liability insurance coverage in amounts and pursuant to terms and conditions customary for our industry, scale, and the nature of our activities. Where local statutory requirements exceed the limits of our existing insurance or local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. This insurance is subject to deductibles and coverage limitations. The availability and cost of maintaining insurance may change over time. See *Item 1A. Risk Factors*.

Human Resources

At December 31, 2018, we had 79 full-time employees, 17 of whom hold Ph.D./PharmD degrees and three of whom hold M.D. degrees. At that date, 47 employees were engaged in research and development, medical, regulatory affairs, and manufacturing related activities and 32 were engaged in finance, legal, administration, commercial, and business development. We consider our relations with our employees to be good. None of our employees is covered by a collective bargaining agreement.

Available Information

We file annual, quarterly and current reports, proxy statements and other documents with the SEC under the Securities Exchange Act of 1934. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Progenics. The SEC's website can be found at http://www.sec.gov . We also make available on or through our website, free of charge, copies of these reports on http://www.progenics.com.

Additional information concerning our business may be available in press releases or other public announcements and quarterly and current reports and documents filed with the SEC. Information on or accessed through our website is not included in our SEC filings.

Item 1A. Risk Factors

General Risks Related to our Business

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

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

The future of our business and operations depends on the success of our development and commercialization programs.

Our business and operations entail a variety of serious risks and uncertainties and are inherently risky. The development programs on which we focus involve novel approaches to human therapeutics and diagnostics. Our product candidates are in clinical development, and in some respects, involve technologies with which we have limited prior experience. We are subject to the risks of failure inherent in the development and commercialization of product candidates based on new technologies. There is little precedent for the successful commercialization of products based on our technologies, and there are a number of technological challenges that we must overcome to complete most of our development efforts. We may not be able to successfully further develop any of our product candidates. We must successfully complete clinical trials and obtain regulatory approvals for potential commercial products. Once approved, if at all, commercial product sales are subject to general and industry-specific local and international economic, regulatory, technological and policy developments and trends. Delays, higher costs or other weaknesses in the manufacturing process at our Somerset, New Jersey manufacturing facility or any of our CMOs could hinder the development and commercialization of our product pipeline. The oncology space in which we operate presents numerous significant risks and uncertainties that may be expected to increase to the extent it becomes more competitive or less favored in the commercial healthcare marketplace.

Failure to realize the anticipated benefits of any strategic acquisition and/or licensing transaction could adversely affect our business, operations and financial condition.

A part of our business strategy has been to identify and advance a pipeline of product candidates by identifying product candidates, technologies and businesses for acquisition and in-licensing that we believe are a strategic fit with our existing business. For example, we recently acquired the AZEDRA manufacturing assets and entered into a sublease agreement for the radiopharmaceutical manufacturing facility, and in 2015 we acquired EXINI Diagnostics A.B. The ultimate success of any strategic transactions entails numerous operational and financial risks, including:

- higher than expected development and integration costs;
- difficulty in combining the technologies, operations and personnel of acquired businesses with our technologies, operations and personnel;
- inherent risks and uncertainties related to our ability to operate newly acquired assets in a manner that achieves our business objectives;
- exposure to unknown liabilities;
- difficulty or inability to form a unified corporate culture across multiple office sites both nationally and internationally;
- inability to retain key employees of acquired businesses;
- disruption of our business and diversion of our management's time and attention; and
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed product candidates, technologies or businesses.

We have limited resources to integrate acquired and in-licensed product candidates, technologies and businesses into our current infrastructure, and we may fail to realize the anticipated benefits of any strategic transactions. Any such failure could have an adverse effect on our business, operations and financial condition.

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

Regulatory approvals are necessary to market product candidates and require demonstration of a product's safety and efficacy through extensive pre-clinical and clinical trials. We may not obtain regulatory approval for product candidates on a timely basis, or at all, and the terms of any approval (which in some countries includes pricing and reimbursement approval) may impose significant restrictions, limitations on use or other commercially unattractive conditions. The process of obtaining FDA and foreign regulatory approvals often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We have had only limited experience in filing and pursuing applications and other submissions necessary to gain marketing approvals. Products under development may never obtain marketing approval from the FDA or other regulatory authorities necessary for commercialization.

We or our regulators may also amend, suspend or terminate clinical trials if we or they believe that the participating patients are being exposed to unacceptable health risks, and after reviewing trial results, we may abandon projects which we previously believed to be promising for commercial or other reasons unrelated to patient risks. During this process, we may find, for example, that results of pre-clinical studies are inconclusive or not indicative of results in human clinical trials, clinical investigators or contract research organizations do not comply with protocols or applicable regulatory requirements, or that product candidates do not have the desired efficacy or have undesirable side effects or other characteristics that preclude marketing approval or limit their potential commercial use if approved. In such circumstances, the entire development program for that product candidate could be adversely affected, resulting in delays in trials or regulatory filings for further marketing approval and a possible need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved. Conducting additional clinical trials or making significant revisions to a clinical development plan would lead to delays in regulatory filings. If clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, we may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development programs for our product candidates may be significantly delayed or terminated altogether.

If the results of any of our clinical trials are not satisfactory or we encounter problems and/or delays enrolling patients, clinical trial supply issues, setbacks in developing drug formulations, including raw material supply, manufacturing, stability or other difficulties, or issues complying with protocols or applicable regulatory requirements, the entire development program for our product candidates could be adversely affected in a material manner.

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

We have limited internal resources with conducting clinical trials, and we rely on or obtain the assistance of others to design, conduct, supervise, or monitor some or all aspects of some of our clinical trials. In relying on these third parties, we have less control over the timing and other aspects of clinical trials than if we conducted them entirely on our own. Problems with the timeliness or quality of the work of a contract research organization or clinical data management organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials and contractual restrictions may make such a change difficult or impossible. These third parties may also have relationships with other entities, some of which may be our competitors. In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA and other foreign regulatory authorities require us to comply with good clinical practices for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

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

Risks Related to Our Commercialized Products RELISTOR and AZEDRA

We have been and expect to continue to be dependent on Bausch to develop and commercialize RELISTOR, exposing us to significant risks.

We rely on Bausch to pursue and complete further development and obtain regulatory approvals for RELISTOR worldwide. At present, our revenue is almost exclusively derived from royalty and milestone payments from our RELISTOR collaboration with Bausch, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue. We are and will be dependent upon Bausch and any other business partners with which we may collaborate in the future to perform and fund development, including clinical testing of RELISTOR, making related regulatory filings and manufacturing and marketing products, including for new indications and in new formulations, in their respective territories. Revenue from the sale of RELISTOR depends entirely upon the efforts of Bausch and its sublicensees, which have significant discretion in determining the efforts and resources they apply to sales of RELISTOR. Bausch may not be effective in obtaining approvals for new indications or formulations, marketing existing or future products or arranging for necessary sublicense or distribution relationships. Our business relationships with Bausch and other partners may not be scientifically, clinically or commercially successful. For example, Bausch has a variety of marketed products and its own corporate objectives, which may not be consistent with our best interests, and may change its strategic focus or pursue alternative technologies in a manner that results in reduced or delayed revenue to us. Bausch may also have commercial and financial interests that are not fully aligned with ours in a given territory or territories - which may make it more difficult for us to fully realize the value of RELISTOR. We may have future disagreements with Bausch, which has significantly greater financial and managerial resources which it could draw upon in the event of a dispute. Such disagreements could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as extensive financial and operational consequences to us and have a material adverse effect on our business, results of operations and financial condition. In addition, independent actions may be taken by Bausch concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property.

Under our agreements with Bausch relating to RELISTOR, we rely on Bausch to, among other things, effectively commercialize the product and manage pricing, sales and marketing practices and inventory levels in the distribution channel. Assessing and reporting on these and other activities and metrics in connection with RELISTOR has been difficult as a result of financial reporting and internal control issues that have surfaced both at Bausch and its predecessor licensee, Salix. Our already limited visibility into the internal operations of Bausch and reliance on Bausch to accurately report information concerning the commercialization of RELISTOR has been further obscured by certain recent events at Bausch. As a result of certain incorrectly recognized revenues, both Bausch's Form 10-K for 2015 and its Form 10-Q for the first quarter of 2016 were filed late, resulting in Bausch receiving notices of default from certain of its noteholders, in each instance. We remain exposed to Bausch's credit risk and the possibility of default under the RELISTOR License Agreement in the event that Bausch were to terminate the agreement at its discretion.

We are also dependent on Bausch for compliance with regulatory requirements as they apply to RELISTOR.

The RELISTOR commercialization program continues to be subject to risk.

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

Under our license agreement with Bausch, Bausch is responsible for obtaining supplies of RELISTOR, including contracting with contract manufacturing organizations for supply of RELISTOR active pharmaceutical ingredient and subcutaneous and oral finished drug product. These arrangements may not be on terms that are advantageous and, as a result of our royalty and other interests in RELISTOR's commercial success, will subject us to risks that the counterparties may not perform optimally in terms of quality or reliability.

Bausch's ability to optimally commercialize either oral or subcutaneous RELISTOR in a given jurisdiction may be impacted by applicable labeling and other regulatory requirements. If clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of RELISTOR, Bausch may stop or significantly slow further development or commercialization of RELISTOR. In such an event, we could be faced with either further developing and commercializing the drug on our own or with one or more substitute collaborators, either of which paths would subject us to the development, commercialization, collaboration and/or financing risks discussed in these risk factors.

We are also aware of other approved and marketed products, as well as product candidates in pre-clinical or clinical development that are intended to target the side effects of opioid pain therapy and are direct competitors to RELISTOR. For instance, there are three approved products that target opioid-induced constipation: MOVANTIK® (naloxegol), AMITIZA® (lubiprostone), and Symproic® (naldemedine) which could compete with RELISTOR. The competitors who have developed these products and product candidates may have superior resources that allow them to implement more effective approaches to sales and marketing. There is no guarantee that RELISTOR will be able to compete commercially with these products. Additionally, there has been growing public concern regarding the use of opioid drugs. Any efforts by the FDA or other governmental authorities to restrict or limit the use of opioids may negatively impact the market for RELISTOR.

Any such significant action adverse to the further development and commercialization of RELISTOR could have a material adverse impact on our business and on the price of our stock.

Our patents are subject to generic challenge, and the validity, enforceability and commercial value of these patents are highly uncertain.

Our ability to obtain and defend our patents impacts the commercial value of our products and product candidates. Third parties have challenged and are likely to continue challenging the patents that have been issued or licensed to us. Patent protection involves complex legal and factual questions and, therefore, enforceability is uncertain. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented, which could negatively impact their commercial value. For example, we (along with Bausch and Wyeth LLC) have received notifications of a Paragraph IV certification for RELISTOR (methylnaltrexone bromide) subcutaneous injection and for RELISTOR (methylnaltrexone bromide) Tablets, for certain patents that are listed in the FDA Orange Book. The certifications resulted from filings by entities such as Mylan Pharmaceuticals Inc., Actavis LLC and Par Sterile Products, LLC of Abbreviated New Drug Applications ("ANDAs") with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection and filings by Actavis Laboratories FL, Inc. seeking to obtain approval to market a generic version of RELISTOR Tablets before some or all of these patents expire. Furthermore, patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, we received notices of opposition to three European patents relating to methylnaltrexone.

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

Pursuant to the RELISTOR license agreement between us and Bausch, Bausch has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement. At the same time, we may incur substantial further costs in supporting the effort to uphold the validity of patents or to prevent infringement. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have previously been and are currently involved in patent litigation, and we expect to be subject to patent litigation in the future. For more information related to our patent litigation and legal proceedings, see *Item 3. Legal Proceedings*.

Our AZEDRA commercialization program is subject to significant risk.

It is very difficult to estimate the commercial potential of recently approved products, 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 and we have not generated any sales as of the date of this filing. 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 pricing for AZEDRA. If pricing for AZEDRA is not 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 have little experience as a company in commercializing products and, prior to the FDA approval and launch 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.

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.

Risks Related to Our Product Candidates

Even if our product candidates obtain marketing approval, our ability to generate revenue will be diminished if our products are not accepted in the marketplace, or if we select pricing strategies for our products that are less competitive than those of our competitors, or fail to obtain acceptable prices or an adequate level of reimbursement for products from third-party payers or government agencies.

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

We are subject to extensive and ongoing regulation, which can be costly and time consuming, may interfere with marketing approval for our product candidates, and can subject us to unanticipated limitations, restrictions, delays and fines.

Our business, products and product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries, and include the Sunshine Act under the Patient Protection and Affordable Care Act ("PPACA"). These agencies and other entities regulate the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, recordkeeping, advertising, promotion and other aspects of our products and product candidates. We cannot guarantee that approvals of product candidates, processes or facilities will be granted on a timely basis, or at all. If we experience delays or failures in obtaining approvals, commercialization of our product candidates will be slowed or stopped. In addition to these uncertainties, the U.S. House of Representatives made several attempts in 2017 to repeal the PPACA and replace it with a curtailed system of tax credits and dissolve an expansion of the Medicaid program. Although such attempts were ultimately unsuccessful, there is considerable uncertainty regarding the future of the current PPACA framework, and any changes will likely take time to unfold. As such, we cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business.

Even if we obtain regulatory approval for a product candidate, the approval may include significant limitations on indicated uses for which the product could be marketed or other significant marketing restrictions.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences.

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

Even if a product receives regulatory approval:

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

Approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are relatively less financially advantageous to us than approval of greater or different scope or subject to an FDA imposed Risk Evaluation and Mitigation Strategy ("REMS") that imposes limits on the distribution or use of the product. While we may develop a product candidate with the intention of addressing a large, unmet medical need, the FDA or other foreign regulatory authorities may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues.

Side effects identified after the product is on the market might hurt sales or result in mandatory safety labeling changes, additional pre-clinical testing or clinical trials, imposition of a REMS, product recalls or withdrawals from the market, reputational harm to us, and lawsuits (including class-action suits).

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

In certain foreign jurisdictions, it cannot be marketed until pricing and reimbursement for the product is also approved.

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

Our relationships with customers and third-party payers are or may become subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

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

If we or our partners are unable to obtain sufficient quantities of the raw and bulk materials needed to make our products or product candidates, development of our products or product candidates or commercialization of our approved products could be slowed or stopped.

We or our partners may not be able to obtain the materials necessary to make a particular product or product candidate in adequate volume and quality. If any materials needed to make a product or product candidate is insufficient in quantity or quality, if a supplier fails to deliver in a timely fashion or at all or if these relationships terminate, we or our partners may not be able to fulfill manufacturing obligations for our products or product candidates, either on our own or through third-party suppliers. A delay or disruption of supplies of our products or product candidates would have a material adverse effect on our business as a whole. Our existing arrangements with suppliers may result in the supply of insufficient quantities of our product candidates needed to accomplish our clinical development programs or commercialization, and we may not have the right and in any event, do not currently have the capability to manufacture these products if our suppliers are unable or unwilling to do so. We currently arrange for supplies of critical raw materials used in production of our product candidates from single sources. We do not have long-term contracts with any of these suppliers. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

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

We or our partners may engage third parties to manufacture our product candidates. We or our partners may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from CMOs at acceptable costs.

In order to commercialize our product candidates successfully, we need to be able to manufacture or arrange for the manufacture of products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. Manufacture of our product candidates, can be complex, difficult to accomplish even in small quantities, difficult to scale-up for large-scale production and subject to delays, inefficiencies and low yields of quality products. The manufacture of radiopharmaceuticals is relatively complex and requires significant capital expenditures. Although we recently acquired the assets comprising the AZEDRA radiopharmaceutical manufacturing facility, we continue to rely on CMOs for our product candidates. The cost of manufacturing our product candidates may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available on a timely basis or at all, our clinical trials or commercialization of our product candidates could be seriously delayed, since these materials are time consuming to manufacture and cannot be readily obtained from third-party sources. We continue to be dependent on a limited number of highly specialized manufacturing and development partners, including single source manufacturers for certain of our product candidates. If we were to lose one or more of these key relationships, it could materially adversely affect our business. Establishing new manufacturing relationships, or creating our own manufacturing capability, would require significant time, capital and management effort, and the transfer of product-related technology and know-how from one manufacturer to another is an inherently complex and uncertain process.

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

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

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

We own or license a number of issued patents. We must obtain, maintain and enforce patent and other rights to protect our intellectual property. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There are many laws, regulations and judicial decisions that dictate and otherwise influence the manner in which patent applications are filed and prosecuted and in which patents are granted and enforced, all of which are subject to change from time to time. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. In addition, we are aware of others who have patent applications or patents containing claims similar to or overlapping those in our patents and patent applications. Accordingly, patent applications owned by or licensed to us may not result in patents being issued. Even if we own or license a relevant issued patent, we may not be able to preclude competitors from commercializing drugs that may compete directly with one or more of our products or product candidates, in which event such rights may not provide us with any meaningful competitive advantage. In the absence or upon successful challenge of patent protection, drugs may be subject to generic competition, which could adversely affect pricing and sales volumes of the affected products.

It is generally difficult to determine the relative strength or scope of a biotechnology or pharmaceutical patent position in absolute terms at any given time. The issuance of a patent is not conclusive as to its validity or enforceability, which can be challenged in litigation or via administrative proceedings. The license agreements from which we derive or out-license intellectual property provide for various royalty, milestone and other payment, commercialization, sublicensing, patent prosecution and enforcement, insurance, indemnification and other obligations and rights, and are subject to certain reservations of rights. While we generally have the right to defend and enforce patents licensed to or by us, either in the first instance or if the licensor or licensee chooses not to do so, we must usually bear the cost of doing so.

Patents have a limited life and expire by law.

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

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

Owned and in-licensed patents relating to the 1404 product candidate have expiration ranges of 2020 to 2029; we view as most significant the composition-of-matter patent on the compound, as well as technetium-99 labeled forms, which expires in 2029 worldwide.

Patent protection for the composition-of-matter patent on PyL compound, radiolabeled form of the compound, as well as methods of use expire in 2030 in the United States. Corresponding patent family members are pending or issued worldwide, all with expirations of 2029. Process improvement patent applications are pending worldwide which, if issued, would expire in 2037.

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

We own patents relating to automated detection of bone cancer metastases through. The patents on this technology expire in 2028. The US patent is currently under reexamination. Applications are pending relating to automated medical image analysis.

With respect to PSMA antibody, currently issued composition-of-matter patents comprising co-owned patents have expirations of 2022 in the U.S. Corresponding foreign counterpart patents will expire 2022. We view all of these patents as significant.

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

Many of our product candidates incorporate intellectual property licensed from third parties. For example, PyL utilizes technology licensed to us from Johns Hopkins University. We could lose the right to patents and other intellectual property licensed to us if the related license agreement is terminated due to a breach by us or otherwise. Our ability to commercialize products incorporating licensed intellectual property would be impaired if the related license agreements were terminated. In addition, we are required to make substantial cash payments, achieve milestones and satisfy other conditions, including filing for and obtaining marketing approvals and introducing products, to maintain rights under our intellectual property licenses. Due to the nature of these agreements and the uncertainties of development, we may not be able to achieve milestones or satisfy conditions to which we have contractually committed, and as a result may be unable to maintain our rights under these licenses. If we do not comply with our license agreements, the licensors may terminate them, which could result in our losing our rights to, and therefore being unable to commercialize, related products.

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

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

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

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

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

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

We have been and expect to continue to be dependent on collaborators for the development, manufacturing and sales of certain products and product candidates, which expose us to the risk of reliance on these collaborators.

In conducting our operations, we currently depend, and expect to continue to depend, on numerous collaborators. Key among these new collaborations, are those with Bayer to develop and commercialize products using our PSMA antibody technology and with Fuji for the development and commercialization of 1404 and bone BSI in Japan. In addition, certain clinical trials for our product candidates may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. These arrangements expose us to the same considerations we face when contracting with third parties for our own trials.

If any of our collaborators breach or terminate its agreement with us or otherwise fail to conduct successfully and in a timely manner the collaborative activities for which they are responsible, the preclinical or clinical development or commercialization of the affected product candidate or research program could be delayed or terminated. We generally do not control the amount and timing of resources that our collaborators devote to our programs or product candidates. We also do not know whether current or future collaboration partners, if any, might pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases or conditions targeted by our collaborative arrangements. Our collaborators are also subject to similar development, regulatory, manufacturing, cyber-security and competitive risks as us, which may further impede their ability to successfully perform the collaborative activities for which they are responsible. Setbacks of these types to our collaborators could have a material adverse effect on our business, results of operations and financial condition.

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

We rely on third parties to perform a variety of functions. We are party to numerous agreements which place substantial responsibility on clinical research organizations, consultants and other service providers for the development of our product candidates. We also rely on medical and academic institutions to perform aspects of our clinical trials of product candidates. In addition, an element of our research and development strategy has been to in-license technology and product candidates from academic and government institutions in order to minimize or eliminate investments in early research. We may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully. Moreover, if third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or applicable protocols, our product candidates may not be approved for marketing and commercialization or such approval may be delayed. If that occurs, we or our collaborators will not be able, or may be delayed in our efforts, to commercialize our product candidates.

Business and Operational Risks

We lack sales and marketing experience.

We have not historically had established sales, marketing or distribution infrastructure but have begun to build out this capability in connection with the launch of AZEDRA in the U.S. We may not be successful in developing an effective commercial infrastructure or in achieving sufficient market acceptance for AZEDRA or other products. We do plan to market and sell products through distribution, co-marketing, co-promotion or licensing arrangements with third parties for territories outside the U.S. We may consider contracting with a third-party professional pharmaceutical detailing and sales organization to perform marketing functions for one or more products. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of product candidates, any revenues we receive will depend primarily on the efforts of third parties. We will not control the amount and timing of marketing resources these third parties devote to our products.

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

From time to time we are involved in legal proceedings and disputes and may be involved in litigation in the future. These proceedings are complex and extended and occupy the resources of our management and employees. These proceedings are also costly to prosecute and defend and may involve substantial awards or damages payable by us if not found in our favor. We may also be required to pay substantial amounts or grant certain rights on unfavorable terms in order to settle such proceedings. Defending against or settling such claims and any unfavorable legal decisions, settlements or orders could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline. For more information regarding legal proceedings, see Item 3 of Part I, and Note 8 in the notes to the consolidated financial statements in Part IV of this Form 10-K.

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

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

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

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected. Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all, and may not be available to us at a reasonable cost in the future. Our current insurance coverage and indemnification arrangements may not be adequate to cover claims brought against us, and are in any event subject to the insuring or indemnifying entity discharging its obligations to us.

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

Research and development work and manufacturing processes with our pipeline products involve the use of hazardous, controlled and/or radioactive materials. We, our CMOs and our distributors are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. In particular we, our CMOs and our distributors are subject to regulation by the U.S. Environmental Protection Agency, U.S. Department of Transportation, Occupational Safety and Health Administration and comparable state regulatory agencies. Despite procedures that we, our CMOs and our distributors implement for handling and disposing of these materials, the risk of accidental contamination or injury cannot be eliminated. In the event of a hazardous waste spill or other accident, we, our CMOs and our distributors could be liable for damages, penalties or other forms of censure. There may be significant costs to comply with applicable environmental laws and regulations in the future, and such costs may be incurred by us directly or passed through to us by our CMOs and our distributors. In the event of the damages, penalties, censures or higher costs outlined above, the efficiency and cost of our research, development and commercialization pipeline may be adversely impacted.

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

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

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

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

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

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

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

Although we currently conduct most of our business in the U.S., we also conduct business internationally, which exposes us to additional risks, including risks associated with foreign legal requirements, economic and political conditions and fluctuations in foreign currency exchange rates. We expect that we will continue to conduct business internationally. These business operations subject us to a number of risks and uncertainties, including but not limited to:

- changes in international regulatory and compliance requirements that could restrict our ability to develop, market and sell our products;
- political and economic instability;
- the impact of any trade or international regulatory policy changes brought about by the new U.S. federal administration;
- diminished protection of intellectual property in some countries outside of the U.S.;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing international operations;
- differing labor regulations and business practices;
- heightened risk of a failure of our overseas employees to comply with U.S. and foreign laws, including export regulations, the FCPA and trade regulations;
- potentially negative consequences from changes in or interpretations of tax laws;
- changes in international medical reimbursement policies and programs;
- financial risks such as longer payment cycles, difficulty collecting accounts receivable and exposure to fluctuations in foreign currency exchange rates;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' and service providers' activities that may fall within the purview of the FCPA or similar foreign laws such as the U.K. Bribery Act; and
- regulatory and compliance risks that relate to data practices and privacy, including those resulting from the EU adopted General Data Protection Regulation, which became effective on May 25, 2018 and imposes monetary penalties for non-compliance.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. These or other similar risks could adversely affect our revenue and profitability.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of our future products. If there is not sufficient reimbursement for our future products, it is less likely that such products will be widely used.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of drugs from other countries, could reduce the net price we receive for any future marketed drugs. As a result, our future drugs might not ultimately be considered cost-effective.

We cannot be certain that reimbursement will be available for AZEDRA or any other drug candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future drugs. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize AZEDRA or any other drug candidates that we develop.

In general, other factors that could affect the demand for, and sales and profitability of our future products include, but are not limited to:

- the timing of regulatory approval, if any, of competitive drugs;
- our or any other of our partners' pricing decisions, as applicable, including a decision to increase or decrease the price of a drug, and the pricing decisions of our competitors;
- the seasonality of patient demand due to health insurance programs;
- government and third-party payor reimbursement and coverage decisions that affect the utilization of our future drugs and competing drugs;
- negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party could cause the sales of our future drugs to decrease or a future drug to be recalled;
- the degree of patent protection afforded our future drugs by patents granted to or licensed by us and by the outcome of litigation involving our or any of our licensor's patents;
- the outcome of litigation involving patents of other companies concerning our future drugs or processes related to production and formulation of those drugs or uses of those drugs; the increasing use and development of alternate therapies;
- the rate of market penetration by competing drugs; and
- the termination of, or change in, existing arrangements with our partners.

Any of these factors could have a material adverse effect on the sales of any drug candidates that we may commercialize in the future.

A significant disruption in our information technology systems or a cyber-security breach could compromise our clinical/patient data or other data, trade secrets and confidential information and adversely affect our business, results of operations and/or financial condition.

We, our current and future contract research organizations, CMOs, licensees and partners are increasingly dependent on critical, complex and interdependent information technology systems to operate our businesses. Like other companies in our industry, we rely on such systems for many aspects of our business. Our systems process, transmit and store information related to research and development, the regulatory approval process, manufacturing, as well as the sale and distribution of our products and product candidates. Our information technology systems, and those of our partners, also manage data such as our financials, intellectual property rights, regulatory information, and other sensitive data relating to our business. Our systems additionally contain confidential personal data and sensitive health information relating to our patients and consumers. Given that we rely on third parties for business purposes such as conducting clinical trials, we are exposed to third-party risk that such sensitive information will be compromised. Although we implement data privacy and safety measures to secure the confidential information that is exchanged between us and third parties, the size and complexity of our information technology systems make them potentially vulnerable to breakdown, malicious cyber-attacks, intrusion, viruses and data security breaches by computer hackers, foreign governments, foreign companies or competitors, or by employee error or malfeasance. Such events may permit unauthorized persons to access, misappropriate and/or destroy sensitive data and result in the impairment or disruption of important business processes, loss or misuse of trade secrets, confidential information or other proprietary intellectual property or public exposure of personal information (including sensitive personal information) of employees, business partners, clinical trial patients, customers and others. Any compromise of our data security could also result in a violation of applicable privacy and other laws and a loss of confidence in our data security measures. If such an event were to occur, our business, results of operations, financial condition and reputation could be adversely affected.

Although we have not experienced a material security breach or cyber-attack, our information technology systems are subject to frequent attacks. While we have implemented protective measures, a significant breakdown, disruption, security breach or cyber-attack may nonetheless occur within our information technology systems. Any of the foregoing could have a material adverse effect on our business, prospects, reputation, operating results and financial condition, including as a result of our being required to make significant investments to fix, fortify or replace our technology systems and/or being subject to lawsuits, fines, penalties or other government action. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems, or those of third parties with which we do business.

If our facility or those of our vendors incur damage or power is lost for a significant length of time, our business will suffer.

We store some of our preclinical and clinical data at our facilities as well as those of our vendors. Any significant degradation or failure of our or our vendors' computer systems could cause us to inaccurately calculate or lose our data.

In addition, our stability samples are stored at our vendors' facilities. If their facilities incur physical damage or have an extended power failure, it could result in a loss of these samples. Loss of our clinical data or stability samples could result in significant delays in our drug development process and could harm our business and operations.

Competitive Risks

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

We are aware of a number of products and product candidates which compete or may potentially compete with our future products. Any of these approved products or product candidates, or others which may be developed in the future, may achieve a significant competitive advantage relative to our future products and, in any event, the existing or future marketing and sales capabilities of these competitors may impair our or our collaborators' ability to compete effectively in the market.

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

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

The extent to which any of our future products achieves market acceptance will depend on competitive factors. Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. We face competition from many for-profit companies and major universities and research institutions in the U.S. and abroad. We face competition from companies marketing existing products or developing new products for diseases and conditions targeted by our technologies. We are aware of a number of products and product candidates which compete or may potentially compete with PSMA-targeted imaging agents and therapeutics, or our other product candidates. We are aware of several competitors, such as Johnson & Johnson subsidiary Janssen Biotech, Inc.; Novartis AG and Pfizer, Inc. in collaboration with Astellas Pharma US, Inc.; Aytu Bioscience, Inc.; Blue Earth Diagnostics, Limited and Bayer HealthCare Pharmaceuticals Inc., which have received approval for or are developing treatments or diagnostics for prostate cancer. Any of these competing approved products or product candidates, or others which may be developed in the future, may achieve a significant competitive advantage relative to 1404, AZEDRA, PyL, 1095, or other product candidates.

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

Financial Risks

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

In November 2016, our subsidiary, MNTX Royalties, entered into a loan agreement (the "Royalty-Backed Loan") with HealthCare Royalty Partners III, L.P. ("HCRP") pursuant to which MNTX Royalties borrowed $50 million and had the ability, subject to mutual agreement with HCRP, to borrow an additional $50 million up to twelve months after the initial closing date of the loan. The loan will be repaid from the royalty payments from the commercial sales of RELISTOR products owed under our agreement with Bausch.

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

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

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

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

As of December 31, 2018, our outstanding non-recourse long term debt amounted to $44.6 million. This level could have adverse consequences for us, including:

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

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

We incur significant costs to develop our product candidates and launch approved products such as AZEDRA. We do not have committed external sources of funding for these projects. We fund our operations, to a significant extent, with the proceeds from capital-raising. We may do so via equity securities issuances in public offerings, through our three-year facility with an investment bank pursuant to which we have sold our stock in at-the-market ("ATM") transactions for net proceeds of approximately $34.7 million and may sell from time to time up to an additional $75.0 million of our stock, or through debt financing. We may also fund operations through collaboration, license, further royalty financings, private placement or other agreements with one or more pharmaceutical or other companies, or the receipt of milestone and other payments for out-licensed products. To the extent we raise additional capital by issuing equity securities, existing stockholders could experience substantial dilution, and if we issue securities other than common stock, new investors could have rights superior to existing stockholders. Any further debt financing that we may obtain may involve operating covenants that restrict our business and significant repayment obligations. To the extent we raise additional funds through new collaboration and licensing arrangements, we may be required to relinquish some rights to technologies or product candidates, or grant licenses on terms that are not favorable to us.

We cannot predict with certainty when we will need additional funds, how much we will need, the form a financing may take or whether additional funds will be available at all. The variability of conditions in global financial and credit markets may exacerbate the difficulty of timing capital raising or other financing, as a result of which we may seek to consummate such transactions substantially in advance of immediate need. Our need for future funding will depend on numerous factors, including the advancement of existing product development projects, the launch of AZEDRA and the availability of new projects; the achievement of events, most of which are out of our control and depend entirely on the efforts of others, triggering milestone payments to us; the progress and success of clinical trials and pre-clinical activities (including studies and manufacturing) involving product candidates, whether conducted by collaborators or us; the progress of research programs carried out by us; changes in the breadth of our research and development programs; the progress of research and development efforts of collaborators; our ability to acquire or license necessary, useful or otherwise attractive technologies; competing technological and market developments; the costs and timing of obtaining, enforcing and defending patent and other intellectual property rights; the costs and timing of regulatory filings and approvals; our ability to manage our growth or contraction; and unforeseen litigation. These factors may be more important with respect to product candidates and programs that involve technologies with which we have limited prior experience. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development or commercialization programs, cause us to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose and may adversely affect our ability to operate as a going concern. We may not be able at a given necessary time to obtain additional funding on acceptable terms, or at all. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize our business.

We have a history of operating losses.

We have incurred substantial losses throughout its history. A large portion of our revenue has historically consisted of upfront and milestone payments from licensing transactions. We reported operating losses for 2018 and 2017, while we reported operating income for 2016, as a result of a milestone payment from Bausch. The timing and amount of any similar transactions in the future is highly unpredictable and uncertain. Without upfront or other such payments, we operate at a loss, due in large part to the significant research and development expenditures required to identify and validate new product candidates and pursue our development efforts. Moreover, we have derived no significant revenue from product sales and have only in the last several years derived revenue from royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur net operating losses and negative cash flow from operations in the future, which could increase significantly if we expand our clinical trial programs and other product development efforts. Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval for and then commercializing AZEDRA and other product candidates, either alone or with others. Our operations may not be profitable even if AZEDRA and any of our other product candidates under development are commercialized. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

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

Our stock price has a history of volatility and may be affected by selling pressure. You should consider an investment in our stock as risky and invest only if you can withstand a significant loss.

Our stock price has a history of significant volatility. It has varied between a high of $9.42 and a low of $3.62 in 2018, between a high of $11.72 and a low of $4.60 in 2017, and between a high of $9.78 and a low of $3.61 in 2016. Factors that may have a significant impact on the market price of our common stock include the results of clinical trials and pre-clinical studies undertaken by us or our collaboration partners; delays, terminations or other changes in development programs; developments in marketing approval efforts; developments in collaborator or other business relationships, particularly regarding RELISTOR, AZEDRA or other significant products or programs; technological innovation or product announcements by us, our collaborators or our competitors; patent or other proprietary rights developments; governmental regulation; changes in reimbursement policies or health care legislation; safety and efficacy concerns about products developed by us, our collaborators or our competitors; our ability to fund ongoing operations; fluctuations in our operating results; general market conditions; and the reporting of or commentary on such matters by the press and others. At times, our stock price has been volatile even in the absence of significant news or developments. The stock prices of biotechnology companies and securities markets generally have been subject to dramatic price swings in recent years, and financial and market conditions during that period have resulted in widespread pressures on securities of issuers throughout the world economy.

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

We expect to issue additional common stock in public offerings, private placements and/or through our October 2018 sales agreement with an investment bank, pursuant to which we may sell from time to time up to $75.0 million of our stock, and to issue options to purchase common stock for compensation purposes. We may issue preferred stock, restricted stock units or securities convertible into or exercisable or exchangeable for our common stock. All such issuances would dilute existing investors and could lower the price of our common stock. Sales of substantial numbers of outstanding shares of common stock could also cause a decline in the market price of our stock. We require substantial external funding to finance our research and development programs and may seek such funding through the issuance and sale of our common stock, which we have done in follow-on primary offerings in 2012, 2013, 2014 and 2018, and ATM transactions in 2017 and 2018. We have a shelf registration statement which may be used to issue up to $250.0 million of common stock and other securities before any underwriter discounts, commissions, and offering expenses. We also have in place registration statements covering shares issuable pursuant to our equity compensation plans, and sales of our securities under them could cause the market price of our stock to decline. Sales by existing stockholders or holders of options or other rights may adversely affect the market price of our common stock.

We are exposed to potential risks from legislation requiring companies to evaluate controls under Section 404 of the Sarbanes-Oxley Act.

The Sarbanes-Oxley Act requires that we maintain effective internal controls over financial reporting and disclosure controls and procedures. Among other things, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act and related regulations ("Section 404"). Compliance with Section 404 requires substantial accounting expense and significant management efforts. Our testing, or the subsequent review by our independent registered public accounting firm, may reveal deficiencies in our internal controls that would require us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities that would require additional financial and management resources and could adversely affect the market price of our common stock. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

We do not intend to pay dividends on our common stock. Until such time as we pay cash dividends, our stockholders must rely on increases in our stock price for appreciation.

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our product candidates. Therefore, we do not intend to pay cash dividends in the foreseeable future. Until such time as we determine to pay cash dividends on our common stock, our stockholders must rely on increases in the market price of our common stock for appreciation of their respective investments.

Other Risks

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

At December 31, 2018, our directors and executive officers together beneficially owned or controlled approximately 4.2% of our outstanding common shares, including shares currently issuable upon option exercises, and our five largest other stockholders held approximately 39.8%. Should these parties choose to act alone or together, they could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could, among other things, have the effect of delaying or preventing a change in control of the Company, adversely affecting our stock price.

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

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

Item 1B. Unresolved Staff Comments

There were no unresolved SEC staff comments regarding our periodic or current reports under the Exchange Act as of December 31, 2018.

Item 2. Properties

At December 31, 2018, we occupied approximately 26,000 square feet of corporate office space located in New York City, pursuant to lease agreements expiring in September 2030 (subject to an early termination right) under which we pay rent and facilities charges including utilities, taxes, and operating expenses.

We also lease approximately 4,000 square feet of office space in Lund, Sweden. The lease term expired on December 31, 2018 and was renewed for an additional three years.

In connection with the February 2019 acquisition of the AZEDRA manufacturing assets, we entered into a sublease agreement for the radiopharmaceutical manufacturing facility located in Somerset, New Jersey. We now occupy approximately 11,400 square feet of space under a sublease agreement expiring in November 2028, under which we pay rent and facilities charges including utilities, taxes and operating expenses.

Item 3. Legal Proceedings

Abbreviated New Drug Application Litigations

RELISTOR Subcutaneous Injection - Mylan

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.

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.

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 as to claim 8 of the '025 patent.

Litigation in the 2:17-cv-06714-SRC-CLW action is underway. Fact discovery in this action has closed and expert discovery deadlines have not yet been set. This action has been consolidated for purposes of trial only with the 2:15-cv-8180 action.

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 stating 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 disqualifying Katten Muchin Rosenman LLP as counsel for Mylan was issued on February 8, 2019, by the Federal Circuit. Merits briefing is currently underway. The deadline for submission of Mylan's opening brief is April 9, 2019.

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.

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.

For each of the above-described proceedings, we and Bausch continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR License Agreement between us and Bausch, Bausch has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement.

We are or may be from time to time involved in various other disputes, governmental and/or regulatory inspections, inquires, 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.

PSMA-617

German District Court Litigation

We announced a lawsuit and associated worldwide patent ownership dispute based on our claims to certain inventions related to PSMA-617, a PSMA-targeted radiopharmaceutical compound under development for the treatment of prostate cancer that is the subject of certain European Patent Applications filed by the University of Heidelberg ("the University").

On November 8, 2018, MIP filed a complaint against the University in the District Court of Mannheim in Germany. In this Complaint, the Company claims that the discovery and development of PSMA-617 was related to work performed under a research collaboration sponsored by MIP. MIP alleged that the University breached certain contracts with MIP and that MIP is the co-owner of inventions embodied in certain worldwide patent filings related to PSMA-617, currently pending in the Europe and the United States that were filed by the University in its own name. On February 27, 2019, Endocyte, Inc., a wholly owned subsidiary of Novartis AG, filed a motion to intervene in the German litigation. Endocyte is the exclusive licensee of the patent rights that are the subject of the German proceedings.

On November 27, 2018, MIP requested that the European Patent Office ("EPO") stay the examination of European Patent (EP) 3 038 996 A1 (EP 14 799 340.6) and of the Divisional Applications EP 18 172 716.5, EP18 184 296.4, and EP 18 203 547.7 pending a decision from the German District court on MIP's Complaint. On December 10, 2018, the EPO granted MIP's request and stayed the examination of the patent and patent applications effective November 27, 2018. Likewise, on December 20, 2018, MIP filed a Confirmation of Ownership with the United States Patent and Trademark Office ("USPTO") in the corresponding US patent applications (US Serial Nos. 15/131,118; 16/038,729 and 16/114988). MIP's filing with the USPTO takes the position that, in light of the collaboration and contracts between MIP and the University, MIP is the co-owner of these pending U.S. patent applications.

Item 4. Mine Safety Disclosures

Not Applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

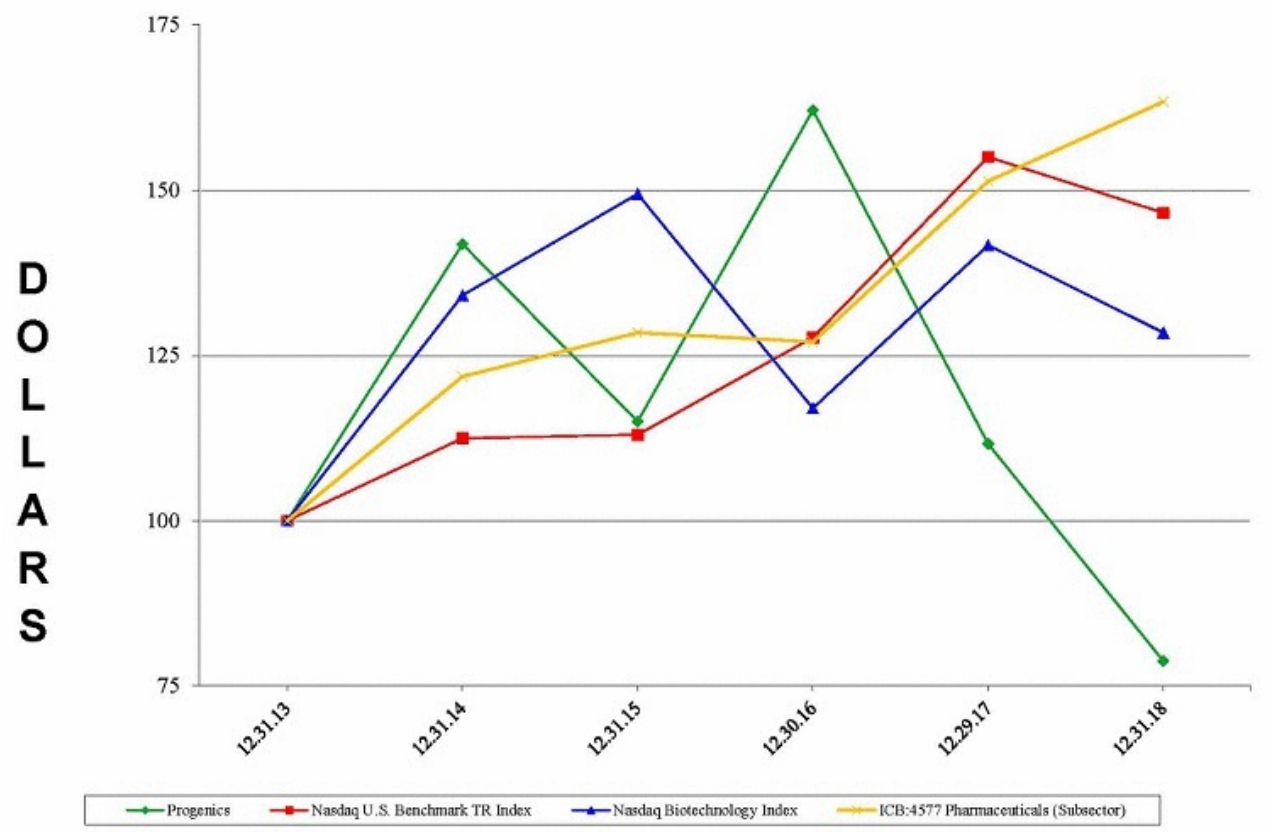
Common Stock

Our common stock is quoted on The Nasdaq Stock Market LLC under the symbol PGNX. On March 11, 2019, there were approximately 63 holders of record of our common stock.

Comparative Stock Performance Graph

The graph below compares, for the past five years, the cumulative stockholder returns on our common stock with the cumulative stockholder returns of (i) the Nasdaq U.S. Benchmark (TR) Index and (ii) the Nasdaq Biotechnology Index, assuming an investment in each of $100 on December 31, 2013.

We changed our comparison peer group from the ICB: 4577 Pharmaceuticals (Subsector) Index to the Nasdaq Biotechnology Index. The reason for this change is that we believe the Nasdaq Biotechnology Index is more reflective of the biotechnology markets that we serve and therefore provides a meaningful comparison of our stock performance to investors. The stock performance graph below includes a comparison of our cumulative total return to both of the selected indices that will be used going forward ((i) Nasdaq U.S. Benchmark (TR) Index and (ii) Nasdaq Biotechnology Index), and the discontinued index (ICB: 4577 Pharmaceuticals (Subsector) Index).



Dividends

We have never paid any dividends, and we currently anticipate that all earnings, if any, will be retained for development of our business and no dividends will be declared in the foreseeable future.

Item 6. Selected Financial Data

The selected historical consolidated statement of operations data presented below for the years ended December 31, 2018, 2017, and 2016 and the historical consolidated balance sheet data as of December 31, 2018 and 2017 have been derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report on Form 10-K. The historical consolidated statement of operations data presented below for the years ended December 31, 2015 and 2014 and the historical consolidated balance sheet data as of December 31, 2016, 2015, and 2014 have been derived from our audited consolidated financial statements that do not appear in this report. The data set forth below should be read in conjunction with *Management's Discussion and Analysis of Financial Condition and Results of Operations* and the consolidated financial statements and related notes included elsewhere herein. The selected historical financial information in this section is not intended to replace our financial statements and the related notes thereto.

	Years Ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Royalty income	$ 14,908	$ 10,965	$ 10,295	$ 6,608	$ 3,101
Other revenue	714	733	59,134	2,068	41,276
Total revenue	15,622	11,698	69,429	8,676	44,377
Expenses:					
Research and development	35,147	42,589	37,569	28,196	28,592
Selling, general and administrative	29,431	24,909	23,356	18,184	15,489
Intangible impairment charges	23,200	-	-	-	2,676
Change in contingent consideration liability	(5,800)	2,600	(4,600)	1,600	1,500
Total operating expenses	81,978	70,098	56,325	47,980	48,257
Other operating income	-	-	-	-	7,250
Operating (loss) income	(66,356)	(58,400)	13,104	(39,304)	3,370
Other (expense) income:					
Interest (expense) income and other income, net	(2,933)	(4,285)	(527)	52	51
Total other (expense) income	(2,933)	(4,285)	(527)	52	51
(Loss) income before income tax benefit (expense)	(69,289)	(62,685)	12,577	(39,252)	3,421
Income tax benefit (expense)	1,632	11,672	(1,844)	133	989
Net (loss) income	(67,657)	(51,013)	10,733	(39,119)	4,410
Net loss attributable to noncontrolling interests	-	-	(73)	(7)	-
Net (loss) income attributable to Progenics	$ (67,657)	$ (51,013)	$ 10,806	$ (39,112)	$ 4,410
Per share amount on net (loss) income attributable to Progenics:					
Basic	$ (0.87)	$ (0.73)	$ 0.15	$ (0.56)	$ 0.06
Diluted	$ (0.87)	$ (0.73)	$ 0.15	$ (0.56)	$ 0.06

	December 31,				
	2018	2017	2016	2015	2014
			(In thousands)		
Consolidated Balance Sheets Data:					
Cash and cash equivalents	$ 137,686	$ 90,642	$ 138,909	$ 74,103	$ 119,302
Working capital	120,683	81,511	131,744	73,556	115,241
Total assets	169,497	145,957	198,986	131,251	161,037
Other liabilities - long term	44,976	67,145	77,867	30,861	29,443
Total stockholders' equity	101,075	63,453	104,762	90,661	124,909

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer. Highlights of our recent progress include the approval, launch and manufacturing of AZEDRA®. Our pipeline includes therapeutic agents designed to precisely target cancer (1095 and PSMA TTC), as well as a prostate-specific membrane antigen ("PSMA") targeted imaging agent for prostate cancer (PyL™).

Our business strategy requires us to manage our business to provide for the continued development, manufacturing and potential commercialization of our proprietary and partnered product candidates. This includes identifying and advancing a pipeline of product candidates by identifying product candidates, technologies and businesses for acquisition and in-licensing that we believe are a strategic fit with our existing business.

Our strategy also calls for us to undertake increased research and development activities and to manage an increasing number of relationships with partners and other third parties, while simultaneously managing the capital necessary to support this strategy. An element of our research and development strategy has been to in-license technology and product candidates.

For additional discussion of our product candidates, license agreements and other arrangements, see *Item 1. Business.*

Recent Developments

In February 2019, we acquired the AZEDRA manufacturing assets for $8.0 million cash consideration and entered into a sublease agreement for the radiopharmaceutical manufacturing facility located in Somerset, New Jersey. The Somerset site serves as the launch facility for AZEDRA and will also provide manufacturing support for our development stage radiopharmaceuticals, including 1095.

Results of Operations

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

	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Total revenue	$ 15,622	$ 11,698	$ 69,429	34%	(83%)
Operating expenses	$ 81,978	$ 70,098	$ 56,325	17%	24%
Operating (loss) income	$ (66,356)	$ (58,400)	$ 13,104	(14%)	(546%)
Net (loss) income	$ (67,657)	$ (51,013)	$ 10,733	(33%)	(575%)
Net (loss) income attributable to Progenics	$ (67,657)	$ (51,013)	$ 10,806	(33%)	(572%)

Revenue

Our sources of revenue during the years indicated below primarily 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):

Source	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Royalty income	$ 14,908	$ 10,965	$ 10,295	36%	7%
Other revenue	714	733	59,134	(3%)	(99%)
Total revenue	**$ 15,622**	**$ 11,698**	**$ 69,429**	34%	(83%)

Royalty income. We recognized royalty income primarily based on the below net sales of RELISTOR as reported to us by Bausch (in thousands). Bausch's reported net sales for the year ended December 31, 2018 were impacted by a non-recurring favorable sales return adjustment, as well as a reduction in channel inventory in the fourth quarter of 2018.

	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
U.S.	$ 96,800	$ 71,100	$ 66,900	36%	6%
Outside U.S.	2,600	2,000	3,700	30%	(46%)
Worldwide net sales of RELISTOR	**$ 99,400**	**$ 73,100**	**$ 70,600**	36%	4%

Royalty income increased by $3.9 million, or 36%, in 2018 compared to 2017 and increased by $0.7 million, or 7%, in 2017 compared to 2016, due primarily to higher net sales of RELISTOR. Bausch launched RELISTOR tablets in the U.S. in September 2016 following receipt of FDA approval in July 2016.

Other revenue. The other revenue remained flat at $0.7 million in 2018 and 2017. The decrease in other revenue of $58.4 million, or 99%, in 2017 compared to 2016 was primarily attributable to the $50.0 million milestone payment under the Bausch license agreement and $7.0 million upfront and milestone payments under the Bayer license agreement, all of which were received in 2016.

Operating Expenses

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

Operating Expenses	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Research and development	$ 35,147	$ 42,589	$ 37,569	(17%)	13%
Selling, general and administrative	29,431	24,909	23,356	18%	7%
Intangible impairment charge	23,200	-	-	100%	N/A
Change in contingent consideration liability	(5,800)	2,600	(4,600)	(323%)	(157%)
Total operating expenses	**$ 81,978**	**$ 70,098**	**$ 56,325**	17%	24%

Research and Development ("R&D")

We do not track fully burdened research and development costs separately for each of our product candidates. We review our research and development expenses by focusing on external and internal development costs. External development costs consist of costs associated with our clinical trials, including pharmaceutical development and manufacturing of clinical trial materials. Included in other costs are external corporate overhead costs that are not specific or allocated to any one program. Internal costs consist of salaries and wages, share-based compensation and benefits, which are not tracked by program as several of our departments support multiple development programs. The following table summarizes the external costs attributable to each program and internal costs (in thousands):

	Years Ended December 31,		
	2018	2017	2016
External Costs			
PyL	$ 9,053	$ 8,633	$ 3,525
AZEDRA	5,982	11,394	10,301
1404	2,645	7,428	8,060
1095	988	671	1,816
Relistor	48	1,126	1,257
Other	3,926	3,263	3,460
Total External Costs	$ 22,642	$ 32,515	$ 28,419
Internal Costs	12,505	10,074	9,150
Total R&D Costs	**$ 35,147**	**$ 42,589**	**$ 37,569**

R&D expenses decreased by $7.4 million, or 17%, in 2018 compared to 2017, primarily attributable to lower external costs associated with the completion of the Phase 2 trial for AZEDRA and the Phase 3 trial for 1404. R&D expenses increased by $5.0 million, or 13%, in 2017 compared to 2016, primarily attributable to higher clinical trial and contract manufacturing costs for PyL and higher consulting fees to support the NDA filing and pre-approval inspection readiness for AZEDRA. Partially offsetting the increase were lower clinical drug supply costs for AZEDRA (as the Phase 2 registrational trial was completed) and lower manufacturing scale-up costs for 1095.

Selling, General and Administrative ("SG&A")

SG&A expenses increased by $4.5 million, or 18%, in 2018 compared to 2017, primarily attributable to higher costs associated with the commercial launch of AZEDRA. SG&A expenses increased by $1.6 million, or 7%, in 2017 compared to 2016, primarily attributable to higher costs associated with building our commercial capabilities in preparation for a potential AZEDRA launch if approved by the FDA, partially offset by depreciation expense. In addition, the 2016 period included an accrual for compensation related to litigation with a former employee, which was not repeated in 2017.

Intangible Impairment Charge

The completion of the 1404 Phase 3 trial, whereby only one of the co-primary endpoints was met, negatively impacted our 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 consolidated statements of operations.

Change in Contingent Consideration Liability

The decrease in the contingent consideration liability of $5.8 million in 2018 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 and we decided not to further invest in 1404, partially offset by higher estimated probability of success of AZEDRA, which was approved on July 30, 2018, and a decrease in the discount period used to calculate the potential milestone payments to former MIP stockholders. The increase in the contingent consideration liability of $2.6 million in 2017 was primarily attributable to a higher estimated probability of success of AZEDRA, as our registrational Phase 2b trial of AZEDRA achieved the primary endpoint under a SPA agreement with the FDA and the reduction in the discount period used to calculate the present value of the contingent consideration liability. The decrease in the contingent consideration liability of $4.6 million in 2016 resulted primarily from a change in the discount rate and sales projections used in calculating the contingent consideration liability.

Other (Expense) Income

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

Other (Expense) Income	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Interest (expense) income, net	(2,912)	(4,038)	(493)	(28%)	719%
Other (expense) income, net	(21)	(247)	(34)	(91%)	626%
Other (expense) income	**$ (2,933)**	**$ (4,285)**	**$ (527)**	(32%)	713%

Total other (expense) income, net decreased by $1.4 million, or 32% in 2018 compared to 2017, primarily attributable to increased interest income due to higher average cash balances and higher interest rates during the current year. The other (expense) income, net increased $3.8 million, or 713%, in 2017 compared to 2016, primarily attributable to interest expense for the Royalty-Backed Loan, which was executed in November 2016.

Income Tax Benefit (Expense)

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

	2018	2017	2016
Income tax benefit (expense)	$ 1,632	$ 11,672	$ (1,844)
Effective tax rate	2.4%	18.6%	14.7%

We account for income taxes using the liability method in accordance with the Accounting Standards Codification ("ASC") Topic740, *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.

During 2018, we recorded an income tax benefit of approximately $1.6 million. The primary driver of this tax benefit is related to the impairment and reclassification of indefinite-lived intangibles for in process research and development assets. Our effective tax rate for 2018 was 2.4%.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation, commonly referred to as the Tax Cuts and Jobs Act ("Tax Act"). As a result of federal tax rate change, we recorded a provisional income tax benefit of approximately $3.7 million in 2017. In accordance with Staff Accounting Bulletin No. 118, we completed the analysis of the impact of the 2017 Tax Act with no change to the provisional amount recorded in 2017. In 2017, we recorded an income tax benefit of approximately $11.7 million in 2017, of which $6.6 million related to the reduction in the federal and state tax rates, $4.8 million related to the use of our naked credit as a source of income to release a portion of our valuation allowance and the remaining $0.2 million related to a refundable AMT credit. Our effective tax rate for 2017 was 18.6%. In 2016, we recorded an income tax expense of approximately $1.8 million in 2016 as a result of an increase in our effective tax rate to 14.7%. Our effective tax rate in 2016 was impacted by our relocation to New York City, which has its own local tax rate and adds to the overall tax rate used for calculating the income tax provision.

Liquidity and Capital Resources

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

	2018	2017	2016
Cash and cash equivalents	$ 137,686	$ 90,642	$ 138,909
Accounts receivable, net	$ 3,803	$ 3,972	$ 4,864
Total assets	$ 169,497	$ 145,957	$ 198,986
Working capital	$ 120,683	$ 81,511	$ 131,744

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 December 31, 2018, we had cash and cash equivalents of approximately $137.7 million, an increase of $47.1 million from $90.6 million at December 31, 2017, reflecting proceeds received from the sale of common stock, partially offset by operating expenses. We expect to continue to have significant cash requirements to support product development activities and the commercial launch of AZEDRA. The amount and timing of 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 December 31, 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 that permitted: (a) the offering, issuance and sale of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the $250.0 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of $75.0 million of our common stock under our sales agreement with Cantor Fitzgerald & Co. ("Cantor") in one or more ATM offerings (the "2017 Sales Agreement").

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. Through December 31, 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.

In October 2018, we filed a new shelf registration statement. 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 $250.0 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the $250.0 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of $75.0 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 2017 Sales Agreement (the "2018 Sales Agreement"). Pursuant to the 2018 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 $75.0 million. The 2018 Sales Agreement may be terminated by Cantor or us at any time upon ten 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.

Cash Flows

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

	2018	2017	2016
Net cash (used in) provided by operating activities	$ (46,752)	$ (54,107)	$ 19,518
Net cash used in investing activities	$ (817)	$ (232)	$ (3,939)
Net cash provided by financing activities	$ 94,717	$ 5,510	$ 49,622

Operating Activities

Net cash used in operating activities during 2018 and 2017 was primarily attributable to funding operating expenses, net of non-cash items, including the intangible impairment charge in 2018 and change in fair value of contingent consideration liability. Net cash provided by operating activities during 2016 was primarily attributable to the milestone payment received from Bausch for the approval of RELISTOR tablets ($50.0 million), partially offset by operating expenses, net of non-cash items.

Investing Activities

Net cash used in investing activities was primarily related to capital expenditures, partially offset by proceeds from the sale of fixed assets.

Financing Activities

Net cash provided by financing activities was primarily attributable to net proceeds from the sale of our common stock in an underwritten public offering in 2018, ATM transactions in 2018 and 2017, net proceeds from the royalty monetization in 2016, and proceeds from the exercise of stock options.

Contractual Obligations

Our funding requirements for the next 12 months and beyond will include required payments under operating leases and fixed payments under license agreements. The following table summarizes our contractual obligations as of December 31, 2018 for future payments under these agreements (in millions):

		Payments Due by Period [1]			
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
Operating leases	$ 26.6	$ 1.9	$ 4.0	$ 4.3	$ 16.4
Fixed payments under license agreements	1.5	0.2	0.4	0.5	0.4
Total	**$ 28.1**	**$ 2.1**	**$ 4.4**	**$ 4.8**	**$ 16.8**

(1) Does not include milestone or contractual payment obligations contingent upon the achievement of certain milestones or events if the amount and timing of such obligations are unknown or uncertain. We may be required to pay additional amounts up to approximately: (i) $90.6 million in contingent milestone payments under our license agreements; (ii) $93.0 million in payments to the former stockholders of MIP, contingent upon achieving specified commercialization events or sales targets; and (iii) $57.1 million in future principal and interest, based upon estimated sales projections, under the Royalty-Backed Loan.

We periodically assess the scientific progress and merits of each of our programs to determine if continued research and development is commercially and economically viable. Certain of our programs have been terminated due to the lack of scientific progress and prospects for ultimate commercialization. Because of the uncertainties associated with research and development in these programs, the duration and completion costs of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete research and development projects in a timely manner or failure to enter into collaborative agreements could significantly increase capital requirements and adversely affect our liquidity.

Our cash requirements may vary materially from those now planned because of results of research and development and product testing, changes in existing relationships or new relationships with licensees, licensors or other collaborators, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory approval process, manufacturing and marketing and other costs associated with the commercialization of products following receipt of regulatory approvals and other factors.

The above discussion contains forward-looking statements based on our current operating plan and the assumptions on which it relies. There could be deviations from that plan that would consume our assets earlier than planned.

Off-Balance Sheet Arrangements and Guarantees

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

Critical Accounting Policies

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. Our significant accounting policies are disclosed in Note 2 to our consolidated financial statements included in this report. 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.

The critical accounting policies we use and the estimates we make are described below. These are policies and estimates that we believe are the most important in portraying our financial condition and results of operations, and that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We have discussed the development, selection, and disclosure of these critical accounting policies and estimates with the Audit Committee of our Board of Directors.

Revenue Recognition. In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2014-09, *Revenue from Contracts with Customers (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. 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 ASU 2014-09, 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.

Share-Based Payment Arrangements. Our share-based compensation of employees includes non-qualified stock options and restricted stock, which are compensatory under ASC 718, *Compensation – Stock Compensation*. We account for share-based compensation to non-employees, including non-qualified stock options and restricted stock, in accordance with ASC 505, *Equity*.

The fair value of each non-qualified stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The model requires input assumptions with respect to (i) expected volatility of our common stock, which is based upon the daily quoted market prices on The Nasdaq Stock Market LLC over a period equal to the expected term, (ii) the period of time over which employees, officers, directors and non-employee consultants are expected to hold their options prior to exercise, (iii) expected dividend yield (zero in our case due to never having paid dividends and not expecting to pay dividends in the future), and (iv) risk-free interest rates for periods within the expected term of the options, which are based on the U.S. Treasury yield curve in effect at the time of grant.

Historical volatilities are based upon daily quoted market prices of our common stock on The Nasdaq Stock Market LLC over a period equal to the expected term of the related equity instruments. We rely only on historical volatility since we believe it is generally viewed as providing the most reliable indication of future volatility. In estimating expected future volatility, we assume it will be consistent with historical; we calculate historical volatility using a simple average calculation; we use available historical data for the length of the option's expected term, and we consistently use a sufficient number of price observations. Since our stock options are not traded on a public market, we do not use implied volatility.

The expected term of options granted represents the period of time that options granted are expected to be outstanding based upon historical data related to exercise and post-termination cancellation activity. The expected term of stock options granted to our Chief Executive Officer ("CEO") and non-employee directors, consultants and officers are calculated separately from stock options granted to other employees.

We apply a forfeiture rate to the number of unvested awards in each reporting period in order to estimate the number of awards that are expected to vest. Estimated forfeiture rates are based upon historical data on vesting behavior of employees. We adjust the total amount of compensation cost 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.

Changes in the assumptions used to compute the fair value of the option awards are likely to affect their fair value and the amount of compensation expense recognized in future periods. A higher volatility, longer expected term and higher risk-free rate increases the resulting compensation expense recognized in future periods. Conversely, a lower volatility, shorter expected term and lower risk-free rate decreases such expense recognized in future periods.

Clinical Trial and Other Research and Development Expenses. Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from contracts with various clinical investigators and clinical research organizations in connection with conducting clinical trials for our product candidates. Such costs are expensed as incurred, and are generally based on the total number of patients in the trial, the rate at which the patients enter the trial and the period over which the clinical investigators and clinical research organizations provide services. We believe that this method best aligns the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates. In addition to clinical trial expenses, we estimate the amounts of other research and development expenses, for which invoices have not been received at the end of a period, based upon communication with third parties that have provided services or goods during the period. Such estimates are subject to change as additional information becomes available.

In–Process Research and Development, Intangible Assets-Technology, and Goodwill. We have a policy for accounting for intangible assets, under which in-process research and development ("IPR&D"), intangible assets-technology, and goodwill are initially measured at fair value and capitalized as intangible assets. Impairment tests for goodwill and IPR&D, which are indefinite-lived intangibles, are performed annually in the fourth quarter, unless impairment indicators require an earlier evaluation. Finite-lived intangible assets, including intangible assets-technology, are evaluated only when impairment indicators are present. IPR&D will be amortized upon and subject to commercialization of the underlying candidates and intangible assets-technology is amortized over the relevant estimated useful life.

Contingent Consideration Liability. The estimated fair value of the contingent consideration liability, initially measured and recorded on the acquisition date, is considered to be a Level 3 instrument and is reviewed quarterly, or whenever events or circumstances occur that indicate a change in fair value. The contingent consideration liability is recorded at fair value at the end of each reporting period.

The estimated fair value is determined based on probability adjusted discounted cash flow and Monte Carlo simulation models that includes significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success and discount rates.

Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively. We record the contingent consideration liability at fair value with changes in estimated fair values recorded in change in contingent consideration liability in our consolidated statements of operations.

Legal Proceedings. From time to time, we may be a party to legal proceedings in the course of our business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. The assessment of whether a loss is probable or reasonably possible, and whether the loss or a range of loss is estimable, often involves a series of complex judgments about future events. We record accruals for contingencies to the extent that the occurrence of the contingency is probable, and the amount of liability is reasonably estimable. If the reasonable estimate of liability is within a range of amounts and some amount within the range appears to be a better estimate than any other, then we record that amount as an accrual. If no amount within the range is a reasonable estimate, then we record the lowest amount as an accrual. Loss contingencies that are assessed as remote are not reported in the financial statements, or in the notes to the consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our primary investment objective is to preserve principal. Our money market funds have interest rates that are variable and totaled $136.1 million at December 31, 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 consolidated results of operations and during the years ended December 31, 2018, 2017, and 2016, our consolidated results of operations were not materially affected by fluctuations in foreign currency exchange rates.

Item 8. Financial Statements and Supplementary Data

See page F-1, *Index to Consolidated Financial Statements.*

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure 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 CEO and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosure. 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 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 our 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 on 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.

Changes in Internal Control over Financial Reporting

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 fiscal quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFO and effected by our Board, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our management is responsible for establishing and maintaining adequate internal control over financial reporting which includes policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorization of management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has used the framework set forth in the report entitled *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), known as COSO, to evaluate the effectiveness of our internal control over financial reporting. Management has concluded that our internal control over financial reporting was effective as of December 31, 2018.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as of December 31, 2018 as stated in their report which is provided below.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Progenics Pharmaceuticals, Inc.

Opinion on Internal Control Over Financial Reporting
We have audited Progenics Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Progenics Pharmaceuticals, Inc. (the "Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a) and our report dated March 14, 2019 expressed an unqualified opinion thereon.

Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting
A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 14, 2019

Item 9B. Other Information

None.

PART III

The information required by the Form 10-K Items listed in the following table will be included under the respective headings specified for such Items in our definitive proxy statement for our 2019 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after December 31, 2018, which proxy statement is incorporated herein by reference:

Item of Form 10-K	Location in 2019 Proxy Statement
Item 10. Directors, Executive Officers and Corporate Governance	*Election of Directors.* *Executive and Other Officers.* *Corporate Governance.* *Code of Business Ethics and Conduct.** *Section 16(a) Beneficial Ownership Reporting and Compliance.* *The full text of our Code of Business Ethics and Conduct is available on our website (www.progenics.com).
Item 11. Executive Compensation	*Executive Compensation.* *Compensation Committee Report.* *Pay Ratio Disclosure.* *Compensation Committee Interlocks and Insider Participation.*
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	*Equity Compensation Plan Information.* *Security Ownership of Certain Beneficial Owners and Management.*
Item 13. Certain Relationships and Related Transactions, and Director Independence	*Certain Relationships and Related Transactions.* *Affirmative Determinations Regarding Director Independence and Other Matters.*
Item 14. Principal Accounting Fees and Services	*Fees Billed for Services Rendered by our Independent Registered Public Accounting Firm.* *Pre-approval of Audit and Non-Audit Services by the Audit Committee.*

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents or the portions thereof indicated are filed as a part of this Annual Report.

(a) Documents filed as part of this Annual Report:

(1) Consolidated Financial Statements of Progenics Pharmaceuticals, Inc.:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2018 and 2017

Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts

Financial statement schedules referred to in Item 12-01 of Regulation S-X and not listed above are inapplicable and therefore have been omitted.

(3) Item 601 Exhibits

Exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately following the signature page of this Report and incorporated herein by reference.

Item 16. Form 10-K Summary

None

PROGENICS PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Progenics Pharmaceuticals, Inc.

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Progenics Pharmaceuticals, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 14, 2019 expressed an unqualified opinion thereon.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2012.

Stamford, Connecticut
March 14, 2019

PROGENICS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 137,686	$ 90,642
Accounts receivable, net	3,803	3,972
Other current assets	2,640	2,256
Total current assets	144,129	96,870
Property and equipment, net	3,944	4,122
Intangible assets, net	6,666	30,369
Goodwill	13,074	13,074
Other assets	1,684	1,522
Total assets	**$ 169,497**	**$ 145,957**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 444	$ 3,359
Accrued expenses	10,533	9,555
Contingent consideration liability	7,050	-
Current portion of debt, net	5,419	2,445
Total current liabilities	23,446	15,359
Long-term debt, net	39,180	47,242
Contingent consideration liability	3,950	16,800
Deferred tax liability	28	1,575
Other liabilities	1,818	1,528
Total liabilities	**68,422**	**82,504**
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value Authorized - 20,000 shares; issued and outstanding - none	-	-
Common stock, $0.0013 par value Authorized - 160,000 shares; issued - 84,742 shares in 2018 and 71,645 shares in 2017	110	93
Additional paid-in capital	713,019	609,829
Treasury stock at cost, 200 shares of common stock	(2,741)	(2,741)
Subscription receivable	-	(2,109)
Accumulated other comprehensive loss	(105)	(33)
Accumulated deficit	(609,208)	(541,586)
Total stockholders' equity	**101,075**	**63,453**
Total liabilities and stockholders' equity	**$ 169,497**	**$ 145,957**

The accompanying notes are an integral part of the financial statements.

PROGENICS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Years Ended December 31,		
	2018	**2017**	**2016**
Revenue:			
Royalty income	$ 14,908	$ 10,965	$ 10,295
Other revenue	714	733	59,134
Total revenue	15,622	11,698	69,429
Operating expenses:			
Research and development	35,147	42,589	37,569
Selling, general and administrative	29,431	24,909	23,356
Intangible impairment charge	23,200	-	-
Change in contingent consideration liability	(5,800)	2,600	(4,600)
Total operating expenses	81,978	70,098	56,325
Operating (loss) income	(66,356)	(58,400)	13,104
Other (expense) income:			
Interest (expense) income and other income, net	(2,933)	(4,285)	(527)
Total other (expense) income	(2,933)	(4,285)	(527)
(Loss) income before income tax (expense) benefit	(69,289)	(62,685)	12,577
Income tax benefit (expense)	1,632	11,672	(1,844)
Net (loss) income	(67,657)	(51,013)	10,733
Net loss attributable to noncontrolling interests	-	-	(73)
Net (loss) income attributable to Progenics	**$ (67,657)**	**$ (51,013)**	**$ 10,806**
Net (loss) income per share attributable to Progenics - basic	**$ (0.87)**	**$ (0.73)**	**$ 0.15**
Weighted-average shares - basic	**77,890**	**70,284**	**70,003**
Net (loss) income per share attributable to Progenics - diluted	**$ (0.87)**	**$ (0.73)**	**$ 0.15**
Weighted-average shares - diluted	**77,890**	**70,284**	**70,155**

The accompanying notes are an integral part of the financial statements.

PROGENICS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(In thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Net (loss) income	$ (67,657)	$ (51,013)	$ 10,733
Other comprehensive loss:			
Foreign currency translation adjustments	(72)	52	(62)
Comprehensive (loss) income	(67,729)	(50,961)	10,671
Comprehensive loss attributable to noncontrolling interests	-	-	(73)
Comprehensive (loss) income attributable to Progenics	**$ (67,729)**	**$ (50,961)**	**$ 10,744**

The accompanying notes are an integral part of the financial statements.

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PROGENICS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Common Stock Subscribed		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Subscription Receivable	Treasury Stock		Noncontrolling Interests	Total Stockholders' Equity
	Number of Shares	Par Value	Number of Shares	Par Value					Number of Shares	Cost		
Balance at December 31, 2015	**70,146**	**$ 91**	**-**	**$ -**	**$ 594,511**	**$ (501,379)**	**$ (26)**	**$ -**	**(200)**	**$ (2,741)**	**$ 205**	**$ 90,661**
Net income	-	-	-	-	-	10,806	-	-	-	-	(73)	10,733
Purchase of noncontrolling interests	-	-	-	-	(239)	-	-	-	-	-	(129)	(368)
Foreign currency translation adjustment	-	-	-	-	-	-	(59)	-	-	-	(3)	(62)
Stock-based compensation expense	-	-	-	-	2,457	-	-	-	-	-	-	2,457
Exercise of stock options	244	1	-	-	1,340	-	-	-	-	-	-	1,341
Balance at December 31, 2016	**70,390**	**$ 92**	**-**	**$ -**	**$ 598,069**	**$ (490,573)**	**$ (85)**	**$ -**	**(200)**	**$ (2,741)**	**$ -**	**$ 104,762**
Net loss	-	-	-	-	-	(51,013)	-	-	-	-	-	(51,013)
Foreign currency translation adjustment	-	-	-	-	-	-	52	-	-	-	-	52
Return of purchase premium for noncontrolling interests	-	-	-	-	15	-	-	-	-	-	-	15
Stock-based compensation expense	-	-	-	-	4,142	-	-	-	-	-	-	4,142
Exercise of stock options	80	-	-	-	469	-	-	-	-	-	-	469
Issuance of common stock in connection with at-the-market offering, net of commissions and issuance costs	855	1	-	-	5,025	-	-	-	-	-	-	5,026
Subscription of common stock in connection with at-the-market offering, net of commissions	-	-	320	-	2,109	-	-	(2,109)	-	-	-	-
Balance at December 31, 2017	**71,325**	**$ 93**	**320**	**$ -**	**$ 609,829**	**$ (541,586)**	**$ (33)**	**$ (2,109)**	**(200)**	**$ (2,741)**	**$ -**	**$ 63,453**
Net loss	-	-	-	-	-	(67,657)	-	-	-	-	-	(67,657)
Foreign currency translation adjustment	-	-	-	-	-	-	(72)	-	-	-	-	(72)
Stock-based compensation expense	-	-	-	-	5,209	-	-	-	-	-	-	5,209
Cumulative effect of ASU 2014-09 adoption	-	-	-	-	-	35	-	-	-	-	-	35
Exercise of stock options	96	-	-	-	467	-	-	-	-	-	-	467
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 commissions ($4,500) and offering expenses ($513)	9,091	12	-	-	69,975	-	-	-	-	-	-	69,987
Balance at December 31, 2018	**84,742**	**$ 110**	**-**	**$ -**	**$ 713,019**	**$ (609,208)**	**$ (105)**	**$ -**	**(200)**	**$ (2,741)**	**$ -**	**$ 101,075**

The accompanying notes are an integral part of the financial statements.

PROGENICS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net (loss) income	$ (67,657)	$ (51,013)	$ 10,733
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Stock-based compensation expense	5,209	4,142	2,457
Depreciation and amortization	1,497	1,121	2,078
Paid in-kind interest	-	(13)	765
Non-cash interest expense	302	247	38
Deferred income tax	(1,548)	(11,435)	1,811
Intangible impairment charge	23,200	-	-
Change in fair value of contingent consideration liability	(5,800)	2,600	(4,600)
Other	-	10	(296)
Changes in assets and liabilities:			
Accounts receivable	204	892	(1,322)
Other current assets	(403)	2,046	1,314
Other assets	(150)	468	(469)
Accounts payable	(2,906)	2,779	243
Accrued expenses	1,009	(6,274)	6,581
Other current liabilities	-	-	(158)
Other liabilities	291	323	343
Net cash (used in) provided by operating activities	(46,752)	(54,107)	19,518
Cash flows from investing activities:			
Purchases of property and equipment	(817)	(269)	(4,286)
Proceeds from sale of fixed assets	-	37	347
Net cash used in investing activities	(817)	(232)	(3,939)
Cash flows from financing activities:			
Net proceeds from public offering of common stock	69,987	-	-
Net proceeds from issuance of long-term debt	-	-	48,650
Net proceeds from issuance of common stock in connection with at-the-market offering	29,653	5,026	-
Proceeds from exercise of stock options	467	469	1,340
Repayment of debt	(5,390)	-	-
Return of estimated interest payment for noncontrolling interest	-	15	(368)
Net cash provided by financing activities	94,717	5,510	49,622
Effect of currency rate changes on cash, cash equivalents and restricted cash	(92)	83	(86)
Net (decrease) increase in cash, cash equivalents and restricted cash	47,056	(48,746)	65,115
Cash, cash equivalents and restricted cash at beginning of period	92,164	140,910	75,795
Cash, cash equivalents and restricted cash at end of period	**$ 139,220**	**$ 92,164**	**$ 140,910**
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 4,660	$ 4,821	$ -
Noncash financing activity			
Subscription receivable	$ (2,109)	$ 2,109	$ -

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 year ended December 31, 2018:

Cash, cash equivalents and restricted cash information	
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	**$ 92,164**
Cash and cash equivalents at end of period	137,686
Restricted cash included in long-term assets at the end of period	1,534
Cash, cash equivalents, and restricted cash at end of period	**$ 139,220**

The accompanying notes are an integral part of the financial statements.

PROGENICS PHARMACEUTICALS, INC.

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

1. Organization and Business

Business

Progenics Pharmaceuticals, Inc. (and its subsidiaries collectively the "Company," "Progenics", "we", or "us") is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer. Highlights of our recent progress include the approval, launch and manufacturing of AZEDRA®. Our pipeline includes therapeutic agents designed to precisely target cancer (1095 and PSMA TTC), as well as a prostate-specific membrane antigen ("PSMA") targeted imaging agent for prostate cancer (PyL™).

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, launching AZEDRA and other related business activities. Certain of our intellectual property rights are held by wholly-owned subsidiaries. Our U.S. operations are presently conducted at our headquarters in New York and our manufacturing facility in Somerset, New Jersey. 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, manufacturing 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.

Revenue

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.

Liquidity

At December 31, 2018, we had $137.7 million in cash and cash equivalents, an increase of $47.1 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 Annual Report on Form 10-K. 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 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. During 2018 and 2017 we raised an additional $29.7 million and $5.0 million, respectively, in at-the-market ("ATM") transactions under a controlled equity offering sales agreement ("Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"). (See **Note 10. Stockholders' Equity** for additional information). During 2016, we raised net proceeds of $48.7 million through a royalty monetization transaction (See **Note 9. Long-Term Debt, Net** for additional information).

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared on the basis of accounting principles generally accepted in the U.S. ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. On an ongoing basis, we evaluate our estimates, including but not limited to those related to collectability of receivables, intangible assets, contingent consideration and legal contingencies. As additional information becomes available or actual amounts become determinable, the recorded estimates are revised and reflected in the operating results. Actual results could differ from those estimates. License and other revenue amounts have been combined in prior periods' financial statements to conform to the current year presentation. In addition, certain amounts in the income tax rate reconciliation have been reclassified within the notes to the consolidated financial statements to conform to current year presentation.

PROGENICS PHARMACEUTICALS, INC.

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

Principles of Consolidation

The 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.

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 in our consolidated statements of comprehensive loss, and the cumulative effect is included in the stockholders' equity section of our consolidated balance sheets. Realized gains and losses denominated in foreign currencies are recorded in operating expenses in our consolidated statements of operations and were not material to our consolidated results of operations for the years ended December 31, 2018, 2017, and 2016.

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 Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2014-09, *Revenue from Contracts with Customers (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 Accounting Standards Codification ("ASC") Topic 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 ASU 2014-09, 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.

PROGENICS PHARMACEUTICALS, INC.

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

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.

The following are our revenue streams from contracts with customers:

Source	2018	2017	2016
Royalty income	$ 14,908	$ 10,965	$ 10,295
Other revenue	714	733	59,134
Total revenue	**$ 15,622**	**$ 11,698**	**$ 69,429**

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).

Included in the $59.1 million other revenue for the year ended December 31, 2016, is $50.7 million we recognized under the RELISTOR License Agreement, of which $50.0 million related to the achievement of a development milestone (FDA approval of RELISTOR tablets) and $0.7 million related to our share of the upfront payment Bausch received from a Canadian-based distributor of RELISTOR. In addition, during 2016, we recognized license revenue of $7.0 million under the license agreement with Bayer, of which $4.0 million related to the upfront payment and $3.0 million related to the achievement of a preclinical development milestones. We are eligible for future milestone and royalty payments under both license agreements with Bausch and Bayer.

We had receivable contract balances of $3.8 million and $4.0 million as of December 31, 2018 and 2017, respectively, primarily related to the royalty revenue stream (see **Note 5. Accounts Receivable**).

Research and Development Expenses

Research and development expenses consist of costs for clinical development and manufacturing of clinical trial materials associated with our research and development activities. Our research and development expenses include:

- External research and development expenses incurred under arrangements with third-parties, such as Contract Research Organizations, or CROs, consultants and Contract Manufacturing Organizations, or CMOs;
- Employee-related expenses, including salaries, benefits, travel and stock-based compensation;
- Facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory supplies; and
- License and sub-license fees.

PROGENICS PHARMACEUTICALS, INC.

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

We expense research and development costs as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received.

At each period end, we evaluate the accrued expense balance related to these activities based upon information received from the suppliers and estimated progress towards completion of the research or development objectives to ensure that the balance is reasonably stated. Such estimates are subject to change as additional information becomes available.

Patents

As a result of research and development efforts conducted by us, we have applied, or are applying, for a number of patents to protect proprietary inventions. All costs associated with patents are expensed as incurred.

Net (Loss) Income Per Share

We prepare earnings per share ("EPS") data in accordance with ASC 260 (Topic 260, *Earnings Per Share*). Basic net (loss) income per share amounts have been computed by dividing net (loss) income attributable to us by the weighted-average number of common shares outstanding during the period. For 2018 and 2017, we reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. For 2016, we reported net income, and the computation of diluted earnings per share is based upon the weighted-average number of our common shares and dilutive effect, determined using the treasury stock method, of potential common shares outstanding including amounts of unrecognized compensation expense. Shares to be issued upon the assumed conversion of the contingent consideration liability are excluded from the diluted earnings per share calculation, if performance conditions have not been met.

Comprehensive (Loss) Income

Comprehensive (loss) income represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive (loss) income includes net (loss) income adjusted for the changes in foreign currency translation adjustment. The disclosures required by ASC 220 (Topic 220, *Comprehensive Income*) for 2018, 2017, and 2016 have been included in the consolidated statements of comprehensive (loss) income. There was no income tax expense/benefit allocated to any component of other comprehensive (loss) income (see **Note 10. Stockholders' Equity** for additional information).

Concentrations of Credit Risk

Financial instruments which potentially subject us to concentrations of risk consist principally of cash, cash equivalents, and receivables. We invest our excess cash in money market funds, which are classified as cash and cash equivalents. We have established guidelines that relate to credit quality, diversification and maturity and that limit exposure to any one issue of securities. We hold no collateral for these financial instruments.

Cash and Cash Equivalents

We consider all highly liquid investments which have maturities of three months or less, when acquired, to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value. Cash and cash equivalents subject us to concentrations of credit risk. At December 31, 2018 and 2017, we had invested approximately $136.1 million and $87.2 million, respectively, in cash equivalents in the form of money market funds with two investment companies and held approximately $1.6 million and $3.4 million, respectively, in three commercial banks.

Restricted Cash

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

Accounts Receivable

We estimate the level of accounts receivable which ultimately will be uncollectable based on a review of specific receivable balances, industry experience and the current economic environment. We reserve for affected accounts receivable an allowance for doubtful accounts. At December 31, 2018, we had no allowance for doubtful accounts.

In-Process Research and Development, Other Identified Intangible Assets and Goodwill

The fair values of in-process research and development ("IPR&D") and other identified intangible assets acquired in business combinations are capitalized. The Company utilizes the "income method", which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs 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 are amortized over the relevant estimated useful life. The IPR&D assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment and any impairment loss is recognized in our 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. The Company determines whether goodwill may be impaired by comparing the fair value of the reporting unit (the Company has determined that it has only one reporting unit for this purpose), calculated as the product of shares outstanding and the share price as of the end of a period, to its carrying value (for this purpose, the Company's total stockholders' equity). No goodwill impairment has been recognized as of December 31, 2018 or 2017.

Fair Value Measurements

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

- Level 1 - Valuations based on unadjusted quoted market 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

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 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.

PROGENICS PHARMACEUTICALS, INC.

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

Recurring Fair Value Measurements

We believe the carrying amounts of our cash equivalents, accounts receivable, other current assets, other assets, accounts payable, and accrued expenses approximated their fair values as of December 31, 2018 and 2017.

The fair value of the contingent consideration liability represents future potential milestone payments related to the MIP acquisition. The fair value of the contingent consideration liability is categorized as a Level 3 instrument, as displayed in Note 4. We record the contingent consideration liability at fair value with changes in estimated fair values recorded in the consolidated statements of operations. We reassess the fair value of the contingent consideration at each reporting period. The contingent consideration liability results from probability adjusted discounted cash flows and Monte Carlo simulation models which include estimates of milestone payments to former MIP stockholders under the acquisition agreement.

Nonrecurring Fair Value Measurements

Our non-financial assets, such as intangible assets and property and equipment, are measured and recorded at fair value on the acquisition date, and if indicators of impairment exist, we assess recoverability by measuring the amount of any impairment by comparing the carrying value of the asset to its then-current estimated fair value (for intangible assets) or to market prices for similar assets (for property and equipment). If the carrying value is not recoverable we record an impairment charge in our consolidated statements of operations. No impairments for property and equipment occurred for the years ended December 31, 2018 and 2017.

Based on the results from the 1404 Phase 3 trial completed in 2018, whereby only one of the co-primary endpoints was met, we changed our Level 3 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 consolidated statements of operations.

Other current assets are comprised of prepaid expenses, interest, and other receivables, all of which are expected to be settled within one year. Restricted cash, included in other assets, represents collateral for letters of credit securing a lease obligation. We believe the carrying value of these assets approximates fair value and are considered Level 1 assets.

Fixed Assets

Leasehold improvements, furniture and fixtures, and equipment are stated at cost. Furniture, fixtures and equipment are depreciated on a straight-line basis over their estimated useful lives. Leasehold improvements are amortized on a straight-line basis over the life of the lease or of the improvement, whichever is shorter. Costs of construction of long-lived assets are capitalized but are not depreciated until the assets are placed in service.

Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation of assets retired or sold are removed from the respective accounts and any gain or loss is recognized in operations. The estimated useful lives of fixed assets are as follows:

Computer equipment (in years)	3
Machinery and equipment (in years)	5 - 7
Furniture and fixtures (in years)	5
Leasehold improvements	Earlier of life of improvement or lease

Deferred Lease Liability and Incentive

Our lease agreements include fixed escalations of minimum annual lease payments and we recognize rental expense on a straight-line basis over the lease terms and record the difference between rent expense and current rental payments as deferred lease liability. Deferred lease incentive includes a construction allowance from our landlord which is amortized as a reduction to rental expense on a straight-line basis over the lease term. As of December 31, 2018, and 2017, our consolidated balance sheets include the following:

	2018	2017
Other current liabilities:		
Deferred lease incentive	$ 26	$ 26
Other liabilities:		
Deferred lease liability	$ 1,541	$ 1,225
Deferred lease incentive	$ 277	$ 303

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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Income Taxes

We account for income taxes in accordance with the provisions of ASC 740 (Topic 740, *Income Taxes*), which requires that we recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (temporary differences) at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain.

In accordance with ASC 718 (Topic 718, *Compensation – Stock Compensation*) and ASC 505 (Topic 505, *Equity*), we have made a policy decision related to intra-period tax allocation, to account for utilization of windfall tax benefits based on provisions in the tax law that identify the sequence in which amounts of tax benefits are used for tax purposes (i.e., tax law ordering). We adopted Accounting Standards Update ("ASU") No. 2016-09, *Compensation – Stock Compensation (Topic 718)* ("ASU 2016-09") on January 1, 2017, which requires that all excess tax benefits and tax deficiencies during the period be recognized in income (rather than in equity) on a prospective basis.

Uncertain tax positions are accounted for in accordance with ASC 740, which prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its financial statements all material uncertain tax positions that we have taken or expect to take on a tax return. ASC 740 applies to income taxes and is not intended to be applied by analogy to other taxes, such as sales taxes, value-add taxes, or property taxes. We review our nexus in various tax jurisdictions and our tax positions related to all open tax years for events that could change the status of our ASC 740 liability, if any, or require an additional liability to be recorded. Such events may be the resolution of issues raised by a taxing authority, expiration of the statute of limitations for a prior open tax year or new transactions for which a tax position may be deemed to be uncertain. Those positions, for which management's assessment is that there is more than a 50% probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to the measurement criteria of ASC 740. We record the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. Any ASC 740 liabilities for which we expect to make cash payments within the next twelve months are classified as "short term." In the event that we conclude that we are subject to interest and/or penalties arising from uncertain tax positions, we will record interest and penalties as a component of income taxes (see **Note 13. Income Taxes** for additional information).

The U.S. Tax Cuts and Jobs Act ("Tax Act") subjects a U.S. shareholder to current tax on global intangible low-taxed income earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that we are permitted to make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as global intangible low-taxed income in future years or provide for the tax expense related to such income in the year the tax is incurred. We have elected to provide for the tax expense in the year the tax is incurred.

Risks and Uncertainties

To date, we have relied principally on external funding, license fees and milestone payments under agreements with Bausch, Bayer and others, out-licensing and asset sale arrangements, and royalties to finance our operations. There can be no assurance that our research and development will be successfully completed, that any products developed will obtain necessary marketing approval by regulatory authorities or that any approved products will be commercially viable. In addition, we operate in an environment of rapid change in technology, and we are dependent upon satisfactory relationships with our partners and the continued services of our current employees, consultants and subcontractors. We are also dependent upon Bausch fulfilling their manufacturing obligations, either on their own or through third-party suppliers. For 2018, 2017, and 2016, the primary sources of our revenues were royalty and milestone payments. There can be no assurance that such revenues will continue. Substantially all of our accounts receivable at December 31, 2018 and 2017 were from the above-named sources.

PROGENICS PHARMACEUTICALS, INC.

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

Legal Proceedings

From time to time, we may be a party to legal proceedings in the course of our business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. The assessment of whether a loss is probable or reasonably possible, and whether the loss or a range of loss is estimable, often involves a series of complex judgments about future events. We record accruals for contingencies to the extent that the occurrence of the contingency is probable, and the amount of liability is reasonably estimable. If the reasonable estimate of liability is within a range of amounts and some amount within the range appears to be a better estimate than any other, then we record that amount as an accrual. If no amount within the range is a reasonable estimate, then we record the lowest amount within the range as an accrual. Loss contingencies that are assessed as remote are not reported in the financial statements, or in the notes to the consolidated financial statements.

Impact of Recently Issued and Adopted Accounting Standards

Recently Adopted

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (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 *Revenue Recognition* section above for additional information)

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments - Overall (Subtopic 825-10): 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 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 consolidated statement of cash flow for the years ended December 31, 2017 and 2016 have been re-casted to conform with the current year presentation under this new guidance.

In January 2017, the FASB issued ASU 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 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.

Recently Issued

In February 2016, the FASB issued ASU 2016-02 ("ASU 2016-02"), *Leases (Topic 842)*. This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and liabilities on their balance sheet that arise from leases with terms longer than 12 months as well as provide disclosures with respect to certain qualitative and quantitative information related to their leasing arrangements. This standard became effective for us on January 1, 2019.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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The FASB has subsequently issued the following amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2019, and which we collectively refer to as the new leasing standards:

- ASU No. 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842,* which permits an entity to elect an optional transition practical expedient to not evaluate under Topic 842 land easements that exist or expired prior to adoption of Topic 842 and that were not previously accounted for as leases under the prior standard, ASC 840, *Leases*.
- ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02.
- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.
- ASU No. 2018-20, *Narrow-Scope Improvements for Lessors*, which contains certain narrow scope improvements to the guidance issued in ASU 2016-02.

We will adopt the new leasing standards on January 1, 2019, using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019. We have reviewed our existing lease contracts and the impact of the new leasing standards on our consolidated financial statements. Upon adoption of the new leasing standards, we expect to recognize a lease liability of approximately $15.3 million and related right-of-use asset of approximately $13.5 million on our consolidated balance sheet. The impact of adoption of the new leasing standards will have no impact to our consolidated statements of operations.

In August 2018, the FASB issued ASU 2018-13 ("ASU 2018-13"), *Fair Value Measurement - Disclosure Framework (Topic 820) : Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. 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 of adopting the updated provisions and the impact of the updated provisions on our consolidated financial statements.

3. Goodwill and Acquired Intangible Assets

Intangible assets and goodwill were initially measured at the acquisition date at estimated fair value and capitalized for the acquisitions of our wholly-owned subsidiaries EXINI and MIP.

The following table summarizes the activity related to goodwill and intangible assets:

	Goodwill	IPR&D	Other Intangible Assets
Balance at January 1, 2017	$ 13,074	$ 28,700	$ 1,881
Amortization expense	-	-	(212)
Balance at December 31, 2017	13,074	28,700	1,669
Reclassification	-	(4,900)	4,900
Amortization expense	-	-	(503)
Impairment	-	(23,200)	-
Balance at December 31, 2018	**$ 13,074**	**$ 600**	**$ 6,066**

The following table reflects the components of the finite-lived intangible assets as of December 31, 2018:

	Gross Amount	Accumulated Amortization	Net Carrying Value
Intangible assets - AZEDRA product rights	$ 4,900	$ 291	$ 4,609
Intangible assets - EXINI technology	2,120	663	1,457
Total	**$ 7,020**	**$ 954**	**$ 6,066**

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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The weighted-average remaining life of the finite-lived intangible assets was approximately seven years at December 31, 2018.

Amortization expense was calculated on a straight-line basis over the estimated useful life of the asset and was $503 thousand, $212 thousand and $212 thousand per year for the years ended December 31, 2018, 2017 and 2016, respectively. Assuming no changes in the gross carrying amount of finite lived intangible assets, the future annual amortization expense related to finite lived intangible assets is expected to be $912 thousand in each of the next five years (2019 through 2023).

4. Fair Value Measurements

We record the contingent consideration liability resulting from our acquisition of MIP at fair value in accordance with ASC 820, *Fair Value Measurement*.

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

		Fair Value Measurements at December 31, 2018		
	Balance at December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 136,052	$ 136,052	$ -	$ -
Total assets	**$ 136,052**	**$ 136,052**	**$ -**	**$ -**
Liabilities:				
Contingent consideration liability	$ 11,000	$ -	$ -	$ 11,000
Total liabilities	**$ 11,000**	**$ -**	**$ -**	**$ 11,000**

		Fair Value Measurements at December 31, 2017		
	Balance 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)
Assets:				
Money market funds	$ 87,231	$ 87,231	$ -	$ -
Total assets	**$ 87,231**	**$ 87,231**	**$ -**	**$ -**
Liabilities:				
Contingent consideration liability	$ 16,800	$ -	$ -	$ 16,800
Total liabilities	**$ 16,800**	**$ -**	**$ -**	**$ 16,800**

The contingent consideration liability of $11.0 million and $16.8 million at December 31, 2018 and 2017, respectively, 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):

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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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):

Calendar Year Net Sales Level	Consideration	Form of Payment at Progenics' Option
$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
	$ 70,000	

We consider this liability a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value was determined based on probability adjusted discounted cash flow and Monte Carlo simulation models that included significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success and discount rates.

The estimated fair value was determined based on probability adjusted discounted cash flow and Monte Carlo simulation models that included significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs were the probabilities of achieving regulatory approval of the development projects and subsequent commercial success, and discount rates.

Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively. We record the contingent consideration liability at fair value with changes in estimated fair values recorded in change in contingent consideration liability in our consolidated statements of operations.

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of the Level 3 inputs at December 31, 2018 and 2017 (in thousands). The 2018 decrease in the contingent consideration liability of $5.8 million was primarily attributable to a decrease in the sales projections and probability of success for 1404, following results from the 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. The 2017 increase in the contingent consideration liability of $2.6 million was primarily attributable to the higher probability of success of AZEDRA used to calculate the potential milestone payments to former MIP stockholders and a reduction in the discount period.

	Fair Value at December 31, 2018	Valuation Technique	Unobservable Input	Range (Weighted-Average)
Contingent Consideration Liability:				
AZEDRA commercialization	$ 7,050	Probability adjusted discounted cash flow model	Probability of success	90%
			Period of expected milestone achievement	2019
			Discount rate	10%
1095 commercialization	450	Probability adjusted discounted cash flow model	Probability of success	18%
			Period of expected milestone achievement	2026
			Discount rate	10%
Net sales targets	3,500	Monte-Carlo simulation	Probability of success	18% - 90%
			Discount rate	10%
Total	**$ 11,000**			

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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	Fair Value at December 31, 2017	Valuation Technique	Unobservable Input	Range (Weighted-Average)
Contingent Consideration Liability:				
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
			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	6,400	Monte-Carlo simulation	Probability of success	16% - 72%
			Discount rate	10%
Total	**$ 16,800**			

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

	Liability - Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	2018	2017
Balance at beginning of period	$ 16,800	$ 14,200
Fair value change included in net loss	(5,800)	2,600
Balance at end of period	**$ 11,000**	**$ 16,800**
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	**$ (5,800)**	**$ 2,600**

5. Accounts Receivable

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 December 31, 2018 and 2017:

	2018	2017
Royalties	$ 3,151	$ 3,683
Other	652	289
Accounts receivable, net	**$ 3,803**	**$ 3,972**

6. Fixed Assets

Fixed assets as of December 31, 2018 and 2017 consisted of the following:

	2018	2017
Machinery and equipment	$ 2,992	$ 2,516
Leasehold improvements	1,734	1,734
Computer equipment	721	714
Furniture and fixtures	878	874
Construction in progress	317	-
Property and equipment, gross	6,642	5,838
Less - accumulated depreciation	(2,698)	(1,716)
Property and equipment, net	**$ 3,944**	**$ 4,122**

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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At December 31, 2018 and 2017, $1.5 million and $1.6 million, respectively, of net leasehold improvements were being amortized over periods of 11.8 years and 12.8 years, under leases with terms through September 30, 2030. We recorded depreciation expense of $1.0 million, $0.9 million, and $1.9 million during 2018, 2017, and 2016, respectively.

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 December 31, 2018 and 2017:

	2018	2017
Accrued payroll and related costs	$ 2,871	$ 2,400
Accrued contract manufacturing costs	2,516	666
Accrued clinical trial costs	2,318	2,570
Accrued consulting and service fee expenses	1,229	1,860
Accrued legal and professional fees	1,191	1,022
Other	408	1,037
Accrued expenses	**$ 10,533**	**$ 9,555**

8. Commitments and Contingencies

Operating Leases

At December 31, 2018, we leased corporate office space in New York City, pursuant to a lease agreement expiring in September 2030 (subject to an early termination right), and additional office space in Lund, Sweden, pursuant to a lease agreement expiring in December 2021.

Rental payments are recognized as rent expense on a straight-line basis over the term of the lease. In addition to rents due under these agreements, we are obligated to pay additional facilities charges, including utilities, taxes and operating expenses.

As of December 31, 2018, future minimum annual payments under all operating lease agreements are as follows:

Years ending December 31,	Minimum Annual Payments
2019	$ 1,935
2020	1,969
2021	2,003
2022	2,134
2023	2,173
Thereafter	16,375
Total	**$ 26,589**

Rental expense totaled approximately $1.9 million, $1.9 million, and $1.2 million for 2018, 2017, and 2016, respectively. For 2018, 2017 and 2016, rent expense exceeded amounts paid by $0.3 million, $0.3 million and $0.2 million, respectively. Additional facility charges, including utilities, taxes, and operating expenses, for 2018, 2017, and 2016 were approximately $0.1 million, $0.1 million, and $1.1 million, respectively.

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Licensing, Service, and Supply Agreements

We have entered into intellectual property-based license and service agreements in connection with product development programs, and have incurred milestone, license and sublicense fees and supply costs, included in research and development expenses, totaling approximately $471 thousand, $343 thousand, and $324 thousand during 2018, 2017, and 2016, respectively.

	Paid from inception/acquisition to December 31, 2018	Future Commitments[1]	Terms
Amgen Fremont, Inc. (formerly Abgenix)	$ 1,350	$ 5,750	Milestones and royalties to use XenoMouse® technology for generating fully human antibodies to PSMA LLC's PSMA antigen.
Former member of PSMA LLC	$ 466	$ 52,188	Annual minimum royalty payments and milestones to use technology related to PSMA.
Selexis Commercial License Agreement	$ 125	$ 1,799	Milestones and royalties to use Selexis technology related to PSMA Antibodies.
University of Zurich and the Paul Scherrer Institute	$ 565	$ 1,125	Annual maintenance and license fee payments, milestones and royalties in respect of licensed technology related to 1404.
University of Western Ontario 2003 Agreement	$ 39	$ 145	Annual minimum royalty, administration and milestone payments in respect of licensed technology related to AZEDRA.
Johns Hopkins University Technology	$ 250	$ 2,685	Annual minimum royalty payments and milestones to use technology related to PyL.

[1] Amounts based on known contractual obligations as specified in the respective license agreements, which are dependent on the achievement or occurrence of future milestones or events and exclude amounts for royalties which are dependent on future sales and are unknown.

In addition, we are planning to out-license or terminate non-germane licenses and service agreements, as to which we have paid $5.0 million through December 31, 2018, and have future commitments of $28.5 million, subject to occurrence of future milestones or events.

Consulting Agreements

As part of our research and development efforts, we have from time to time entered into consulting agreements with external scientific specialists. These agreements contain various terms and provisions, including fees to be paid by us and royalties, in the event of future sales, and milestone payments, upon achievement of defined events, payable by us. Certain of these scientists are advisors to us, and some have purchased our common stock or received stock options which are subject to vesting provisions. We have recognized expenses with regard to the consulting agreements of $300 thousand, $326 thousand, and $164 thousand for 2018, 2017, and 2016, respectively.

Legal Proceedings

On January 4, 2017, we settled all claims against us under a federal action brought in 2010 by a former employee, where such former employee had complained that we had violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating him. In connection with this settlement, we and the former employee exchanged mutual releases and we paid an aggregate sum of $4.0 million to the former employee and his attorneys.

Abbreviated New Drug Application Litigations

RELISTOR Subcutaneous Injection - Mylan

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.

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.

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 as to claim 8 of the '025 patent.

Litigation in the 2:17-cv-06714-SRC-CLW action is underway. Fact discovery in this action has closed and expert discovery deadlines have not yet been set. This action has been consolidated for purposes of trial only with the 2:15-cv-8180 action.

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 stating 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 disqualifying Katten Muchin Rosenman LLP as counsel for Mylan was issued on February 8, 2019, by the Federal Circuit. Merits briefing is currently underway. The deadline for submission of Mylan's opening brief is April 9, 2019.

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.

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.

For each of the above-described proceedings, we and Bausch continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between Progenics and Bausch, Bausch has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement.

We are or may be from time to time involved in various other disputes, governmental and/or regulatory inspections, inquires, 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.

PSMA-617

German District Court Litigation

We announced a lawsuit and associated worldwide patent ownership dispute based on our claims to certain inventions related to PSMA-617, a PSMA-targeted radiopharmaceutical compound under development for the treatment of prostate cancer that is the subject of certain European Patent Applications filed by the University of Heidelberg ("the University").

On November 8, 2018, MIP filed a complaint against the University in the District Court of Mannheim in Germany. In this Complaint, the Company claims that the discovery and development of PSMA-617 was related to work performed under a research collaboration sponsored by MIP. MIP alleged that the University breached certain contracts with MIP and that MIP is the co-owner of inventions embodied in certain worldwide patent filings related to PSMA-617, currently pending in the Europe and the United States that were filed by the University in its own name. On February 27, 2019, Endocyte, Inc., a wholly owned subsidiary of Novartis AG, filed a motion to intervene in the German litigation. Endocyte is the exclusive licensee of the patent rights that are the subject of the German proceedings.

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

On November 27, 2018, MIP requested that the European Patent Office ("EPO") stay the examination of European Patent (EP) 3 038 996 A1 (EP 14 799 340.6) and of the Divisional Applications EP 18 172 716.5, EP18 184 296.4, and EP 18 203 547.7 pending a decision from the German District court on MIP's Complaint. On December 10, 2018, the EPO granted MIP's request and stayed the examination of the patent and patent applications effective November 27, 2018. Likewise, on December 20, 2018, MIP filed a Confirmation of Ownership with the United States Patent and Trademark Office ("USPTO") in the corresponding US patent applications (US Serial Nos. 15/131,118; 16/038,729 and 16/114988). MIP's filing with the USPTO takes the position that, in light of the collaboration and contracts between MIP and the University, MIP is the co-owner of these pending U.S. patent applications.

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 will be applied solely to the payment of interest on the loan, with any royalties in excess of the interest amount retained by us. Beginning on March 31, 2018, 50% of RELISTOR royalty payments received since the immediately preceding payment date in excess of accrued interest on the loan will be used to repay the principal of the loan, with the balance retained by us. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid. The loan has a maturity date of June 30, 2025. Upon the occurrence of certain triggers in the loan agreement, or if HCRP so elects on or after January 1, 2018, all of the RELISTOR royalty payments received after the immediately preceding payment date shall be applied to the payment of interest and repayment of principal until the principal of the loan is fully repaid. In the event of such an election by HCRP, we have the right to repay the loan without any prepayment penalty.

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.

As of December 31, 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.

Future principal payments, based upon estimated sales projections, under the Royalty-Backed Loan as of December 31, 2018, are as follows:

2019	$	5,688
2020		6,989
2021		13,125
2022		19,560
Total payments	**$**	**45,362**

Interest expense, including amortization of debt discount, related to the Royalty-Backed Loan for the year ended December 31, 2018 and 2017 was approximately $5.0 million and $5.1 million, respectively.

10. Stockholders' Equity

Common Stock and Preferred Stock

We are authorized to issue 160.0 million shares of our common stock, par value $.0013, and 20.0 million shares of preferred stock, par value $.001. The Board of Directors (the "Board") has the authority to issue common and preferred shares, in series, with rights and privileges as determined by the Board.

Shelf Registration

During the first quarter of 2017, we filed a shelf registration statement that permitted: (a) the offering, issuance and sale of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the $250.0 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of $75.0 million of our common stock under our sales agreement with Cantor Fitzgerald & Co. ("Cantor") in one or more at-the-market ("ATM") offerings (the "2017 Sales Agreement").

During 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 3.9 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 $27.5 million at an average selling price of $7.45 per share.

During the fourth quarter of 2017, we sold 0.9 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 $5.0 million at an average selling price of $6.06 per share. At December 31, 2017, we had 0.3 million shares of our common stock subscribed in ATM transactions under the sales agreement for net proceeds, after deducting commissions and other transaction costs, of approximately $2.1 million at an average selling price of $6.79 per share. Accordingly, we have recorded a subscription receivable of $2.1 million as a reduction of stockholders' equity in our consolidated balance sheet at December 31, 2017.

In October 2018, we filed a new shelf registration statement. 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 $250.0 million of our common stock, preferred stock, debt securities, warrants, rights and/or units; and (b) as part of the $250.0 million, the offering, issuance and sale by us of up to a maximum aggregate offering price of $75.0 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 2017 Sales Agreement (the "2018 Sales Agreement"). Pursuant to the 2018 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 $75.0 million. The 2018 Sales Agreement may be terminated by Cantor or us at any time upon ten 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.

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 5.0 million 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.

PROGENICS PHARMACEUTICALS, INC.

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

- The 2005 Stock Incentive Plan (the "2005 Plan"), which authorized the issuance of up to 11.45 million 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.

- The 2018 Performance Incentive Plan (the "2018 Plan"), pursuant to which we are authorized to issue up to 4.8 million 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 year ended December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at January 1, 2018	5,535	$ 7.25	6.04
Granted	1,566	$ 6.93	
Exercised	(96)	$ 4.85	
Cancelled	(483)	$ 7.97	
Expired	(258)	$ 16.05	
Outstanding at December 31, 2018	**6,264**	**$ 6.79**	**6.02**
Exercisable at December 31, 2018	**4,242**	**$ 6.42**	**4.78**
Vested and expected to vest at December 31, 2018	**5,887**	**$ 6.75**	**5.84**

The weighted average fair value of options granted during 2018, 2017, and 2016 was $4.56, $6.96, and $3.24 per share, respectively.

The total intrinsic value (the excess of the market price over the exercise price) for stock options outstanding, exercisable, and vested and expected to vest, was zero as of December 31, 2018. The total intrinsic value for stock options exercised during 2018, 2017, and 2016 was $173 thousand, $233 thousand, and $476 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.

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

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 U.S. 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.

The following table presents assumptions used in computing the fair value of option grants during 2018, 2017, and 2016:

	2018	2017	2016
Risk-free interest rate	2.72%	2.17%	1.53%
Expected life (in years)	6.67	6.76	6.77
Expected volatility	69%	72%	74%
Expected dividend yield	--	--	--

Stock-based compensation expense for the years ended December 31, 2018, 2017, and 2016 was recorded in our consolidated statement of operations as follows:

	2018	2017	2016
Research and development expenses	$ 1,760	$ 1,371	$ 843
General and administrative expenses	3,449	2,771	1,614
Total stock-based compensation expense	**$ 5,209**	**$ 4,142**	**$ 2,457**

At December 31, 2018, unrecognized stock-based compensation expense related to stock options was approximately $5.2 million and is expected to be recognized over a weighted average period of approximately 2.1 years.

12. Employee Savings Plan

The terms of the amended and restated Progenics Pharmaceuticals 401(k) Plan (the "401(k) Plan"), among other things, allow eligible employees to participate in the Amended Plan by electing to contribute to the 401(k) Plan a percentage of their compensation to be set aside to pay their future retirement benefits. We matched 50% of employee contributions equal to 1% - 10% of compensation during the three years ended December 31, 2018, made by eligible employees to the 401(k) Plan (the "Matching Contribution"). In addition, we may also make a discretionary contribution each year on behalf of all participants who are non-highly compensated employees. We made Matching Contributions of approximately $381 thousand, $302 thousand, and $281 thousand to the 401(k) Plan for the years ended December 31, 2018, 2017, and 2016, respectively. No discretionary contributions were made during those years.

13. Income Taxes

We account for income taxes using the liability method in accordance with ASC 740 *Income Taxes*. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation, commonly referred to as the Tax Cuts and Jobs Act ("Tax Act"). As a result of the federal tax rate change, we recorded a provisional income tax benefit of approximately $3.7 million in 2017. In accordance with Staff Accounting Bulletin No. 118, we completed the analysis of the impact of the 2017 Tax Act, with no change to the provisional amount recorded in 2017.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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In 2018, we recorded an income tax benefit of approximately $1.6 million. The primary driver of this tax benefit is related to the impairment and reclassification of indefinite-lived intangibles for in process research and development assets. Our effective tax rate for 2018 was 2.4%. In 2017, we recorded an income tax benefit of approximately $11.7 million, of which $6.6 million related to the reduction in the federal and state tax rates, $4.8 million related to the use of our naked credit as a source of income to release a portion of our valuation allowance and the remaining $0.2 million related to a refundable AMT credit. Our effective tax rate for 2017 was 18.6%. In 2016, we recorded an income tax expense of approximately $1.8 million as a result of an increase in our effective tax rate to 14.7%. Our effective tax rate in 2016 was impacted by our relocation to New York City, which has its own local tax rate and adds to the overall tax rate used for calculating the income tax provision.

We have completed calculations through June 30, 2016, under Internal Revenue Code Section 382, the results of which indicate that past ownership changes will limit annual utilization of net operating losses ("NOLs") in the future. Ownership changes subsequent to June 30, 2016, may further limit the future utilization of net operating loss and tax credit carry-forwards as defined by the federal and state tax codes.

The components of the (benefit from) provision for income taxes from continuing operations during the three years ending December 31, 2018 consisted of the following:

	2018	2017	2016
Current taxes:			
United States	$ (2)	$ 3	$ 11
Foreign	-	-	-
State	(82)	(16)	22
Total current taxes	**$ (84)**	**$ (13)**	**$ 33**
Deferred taxes:			
United States	$ (1,188)	$ (8,777)	$ -
Foreign	-	-	-
State	(360)	(2,882)	1,811
Total deferred taxes	**$ (1,548)**	**$ (11,659)**	**$ 1,811**
(Benefit from) provision for income taxes	**$ (1,632)**	**$ (11,672)**	**$ 1,844**

Deferred tax assets and liabilities as of December 31, 2018 and 2017 consisted of the following:

	2018	2017
Deferred tax assets:		
Depreciation	$ -	$ 100
Research & Experimental and Orphan Drug tax credit carry-forwards	35,435	33,496
NYS investment tax credit carry-forwards	1,282	1,284
Net operation loss carry-forwards	188,588	177,313
Capitalized research and development expenditures	1,066	3,066
Stock compensation	5,236	5,666
Other items	819	1,279
Total gross deferred tax assets	232,426	222,204
Less valuation allowance	(232,174)	(217,382)
Deferred tax assets	252	4,822
Deferred tax liabilities:		
Indefinite-lived intangibles	(136)	(6,397)
Depreciation and amortization	(144)	-
Deferred tax liabilities	(280)	(6,397)
Net deferred tax liability	**$ (28)**	**$ (1,575)**

We maintain a tax valuation allowance on deferred tax assets considering our history of taxable losses and the uncertainty regarding our ability to generate sufficient taxable income in the future to utilize these deferred tax assets. For 2018 and 2017, we incurred net losses for tax purposes. We recognized a full tax valuation against deferred tax assets at December 31, 2018 and 2017. In 2018 and 2017, we recognized deferred tax liabilities of $0.03 million and $1.6 million, respectively, to reflect the net tax effects related to the impairment and reclassification of indefinite-lived intangibles for in process research and development assets.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
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The following is a reconciliation of the U.S. statutory income tax rate to our effective tax rate for the years ended December 31, 2018, 2017, and 2016:

	2018	2017	2016
U.S. Federal statutory rate	21.0%	34.0%	34.0%
State income taxes, net of Federal benefit	0.9%	1.5%	10.8%
Foreign rate differential	0.0%	(0.6%)	2.6%
Research and experimental and Orphan Drug tax credit	2.3%	6.4%	(50.6%)
Effect of federal and state tax rate changes	0.3%	(6.1%)	(43.0%)
Tax Reform Impact	0.0%	13.9%	0.0%
Change in fair value of contingent consideration liability	1.8%	(1.4%)	(12.4%)
Stock option shortfalls	(2.2%)	(3.1%)	22.3%
Other	(0.5%)	(0.1%)	0.1%
Change in valuation allowance	(21.2%)	(25.9%)	50.9%
Effective tax rate	**2.4%**	**18.6%**	**14.7%**

As of December 31, 2018, we had available, for tax return purposes, unused federal NOLs of approximately $712.7 million, of which $664.1 million of NOLs generated prior to 2018 will expire in various years from 2019 to 2037 and $48.6 million of NOLs generated in 2018 can be carried forward indefinitely. Also, we had available, for tax return purposes, unused state NOLs of approximately $577.3 million, which will expire in various years from 2030 to 2038 and unused foreign NOLs of approximately $10.3 million, which can be carried forward indefinitely.

We have reviewed our nexus in various tax jurisdictions and our tax positions related to all open tax years for events that could change the status of our ASC 740 *Income Taxes* liability, if any, or require an additional liability to be recorded. We have not, as of yet, conducted a study of our research and experimental ("R&E") credit carry-forwards. Such a study might result in an adjustment to our R&E credit carry-forwards, but until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under ASC 740-10 except for uncertain tax positions acquired in connection with the MIP acquisition. A full valuation allowance has been provided against our R&E credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the statements of operations and comprehensive loss if an adjustment was required.

As of December 31, 2018, we are subject to federal, foreign, and state income tax. Open tax years relate to years in which unused net operating losses were generated or, if used, for which the statute of limitation for examination by taxing authorities has not expired. Our open tax years extend back to 1997. No amounts of interest or penalties were recognized in our consolidated statements of operations or consolidated balance sheets as of and for the years ended December 31, 2018, 2017, and 2016.

Our R&E and Orphan Drug tax credit carry-forwards of approximately $36.1 million at December 31, 2018 expire in various years from 2019 to 2038.

As of December 31, 2018 and 2017, we have not recognized any liability for uncertain tax positions, because of our full valuation allowance. We will recognize interest and penalties related to these positions, should such costs be assessed. The recognition of unrecognized tax benefits would not affect our effective tax rate because the tax benefit would be offset by an increase in our valuation allowance.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2018 and 2017.

	2018	2017
Beginning uncertain tax benefits	$ 1,951	$ 2,661
Prior year - increases (decreases)	-	(710)
Current year - increases (decreases)	-	-
Settlements	-	-
Expired statuses	(7)	-
Ending uncertain tax benefits	**$ 1,944**	**$ 1,951**

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

14. Net (Loss) Income Per Share

Our basic net (loss) income per share attributable to Progenics amounts have been computed by dividing net (loss) income attributable to Progenics by the weighted-average number of common shares outstanding during the period. For 2018 and 2017 we reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. As a result, basic and diluted EPS are the same for 2018 and 2017. For 2016, we reported net income, and the computation of diluted earnings per share is based upon the weighted-average number of our common shares and dilutive effect of stock options (determined using the treasury stock method).

In applying the treasury stock method for the calculation of diluted EPS, amounts of unrecognized compensation expense are required to be included in the assumed proceeds in the denominator of the diluted EPS calculation unless they are anti-dilutive. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls, for purposes of diluted EPS calculation, excluding the impact of deferred tax assets. This policy decision will apply when we have net income and windfall tax benefits/shortfalls are realizable.

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

	Net (loss) income attributable to Progenics (Numerator)	Weighted-average shares outstanding (Denominator)	Per share amount
2018			
Basic and diluted	$ (67,657)	77,890	$ (0.87)
2017			
Basic and diluted	$ (51,013)	70,284	$ (0.73)
2016			
Basic	$ 10,806	70,003	$ 0.15
Dilutive effect of stock options	-	152	
Diluted	$ 10,806	70,155	$ 0.15

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 the diluted net (loss) income per share:

	2018	2017	2016
Stock options	3,794	2,395	3,577
Contingent consideration liability[(1)]	2,619	2,824	1,644
Total securities excluded	**6,413**	**5,219**	**5,221**

(1) Calculated as follows: (a) the contingent consideration liability balance at December 31 divided by (b) the closing stock price of our common stock on the last day of trading of the fiscal year.

PROGENICS PHARMACEUTICALS, INC.

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

15. Unaudited Quarterly Results (unaudited)

Summarized quarterly financial data during 2018 and 2017 are as follows:

	2018 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	$ 3,189	$ 3,878	$ 5,317	$ 3,238
Operating expenses	$ 15,607	$ 18,216	$ 30,365	$ 17,790
Operating loss	$ (12,418)	$ (14,338)	$ (25,048)	$ (14,552)
Net loss	$ (13,424)	$ (15,172)	$ (24,357)	$ (14,704)
Net loss per share - basic and diluted	$ (0.19)	$ (0.20)	$ (0.30)	$ (0.17)

	2017 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	$ 2,347	$ 2,765	$ 2,697	$ 3,889
Operating expenses	$ 17,600	$ 18,325	$ 17,002	$ 17,171
Operating loss	$ (15,253)	$ (15,560)	$ (14,305)	$ (13,282)
Net loss	$ (16,360)	$ (16,636)	$ (15,352)	$ (2,665)
Net loss per share - basic and diluted	$ (0.23)	$ (0.24)	$ (0.22)	$ (0.04)

16. Subsequent Event

In February 2019, we acquired the AZEDRA manufacturing assets for $8.0 million cash consideration and entered into a sublease agreement for the radiopharmaceutical manufacturing facility located in Somerset, New Jersey. The Somerset site serves as the launch facility for AZEDRA and will also provide manufacturing support for the Company's development stage radiopharmaceuticals, including 1095. We also secured the long-term supply of iodine necessary for the production of both AZEDRA and 1095. The production of AZEDRA uses a proprietary Ultratrace ® process which concentrates the MIBG targeted radiolytic activity by eliminating non-therapeutic "cold" MIBG molecules, giving AZEDRA a uniquely high specific activity. We are still evaluating the accounting implications of this transaction.

SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

Allowance for Doubtful Accounts

Year ended December 31,	Beginning Balance	Additions Charged to General and Administrative Expenses	Deductions Accounts Written Off During Period	Ending Balance
	(in thousands)			
2018	$ -	$ -	$ -	$ -
2017	$ -	$ -	$ -	$ -
2016	$ 10	$ -	$ (10)	$ -

EXHIBIT INDEX

Exhibit Number *	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(2)	Amended and Restated By-laws of the Registrant.
4.1(3)	Specimen Certificate for Common Stock, $0.0013 par value per share, of the Registrant.
10.1(23)	Progenics Pharmaceuticals, Inc. 2018 Performance Incentive Plan.
10.2(24)	Settlement and License Agreement by and among the Registrant, Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Wyeth LLC, and Actavis LLC., entered into as of May 25, 2018.
10.3(25)	Settlement and License Agreement by and among the Registrant, Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Wyeth LLC, and Par Sterile Products, LLC and Par Pharmaceutical, Inc., dated May 10, 2018.
10.5(4) ‡	Amended and Restated 1996 Stock Incentive Plan
10.6.3(5) ‡	Amended 2005 Stock Incentive Plan
10.6.4(6) ‡	Form of Non-Qualified Stock Option Award Agreement
10.6.5(6) ‡	Form of Restricted Stock Award Agreement
10.7(7) ‡	Form of Indemnification Agreement
10.21.1(9)	Amended and Restated Agreement of Lease, dated October 28, 2009, between BMR-Landmark at Eastview LLC and the Registrant.
10.25(10) †	Option and License Agreement, dated May 8, 1985, by and between the University of Chicago and UR Labs, Inc., as amended by (i) Amendment to Option and License Agreement, dated September 17, 1987, by and between the University of Chicago and UR Labs, Inc. and (ii) Second Amendment to Option and License Agreement, dated March 3, 1989, by and among the University of Chicago, ARCH Development Corporation and UR Labs, Inc.
10.26(11)	Membership Interest Purchase Agreement, dated April 20, 2006, between the Registrant and Cytogen Corporation.
10.27(11) †	Amended and Restated PSMA/PSMP License Agreement, dated April 20, 2006, by and among the Registrant, Cytogen Corporation and PSMA Development Company LLC.
10.34(12) †	Collaboration Agreement, effective June 14, 2005, by and between Seattle Genetics, Inc. and PSMA Development Company LLC.
10.37(13) †	License Agreement, dated February 3, 2011, by and between Salix Pharmaceuticals, Inc., the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Excelsior Life Sciences Ireland Limited.
10.37.1(13) †	2010 Agreement Related to Progenics' MNTX In-License, dated February 3, 2011, by and among the University of Chicago, acting on behalf of itself and ARCH Development Corporation, the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Salix Pharmaceuticals, Inc.
10.38(14) †	Stock Purchase and Sale Agreement, dated January 16, 2013, by and between Molecular Insight Pharmaceuticals, Inc., its Stockholders, the Registrant, and Highland Capital Management, L.P., as Stockholders Representative.
10.39(14) †	License Agreement, dated September 1, 2012, by and between FUJIFILM RI Pharma Co., Ltd. and Molecular Insight Pharmaceuticals, Inc.
10.40(15) †	License Agreement, dated May 4, 2012, between Molecular Insight Pharmaceuticals, Inc., the University of Zurich and the Paul Scherrer Institute.
10.41(16)	License Agreement, dated December 15, 2000, between Molecular Insight Pharmaceuticals, Inc. and The Board of Governors of the University of Western Ontario.
10.43(17)	Controlled Equity Offering℠ Sales Agreement, dated October 12, 2018, by and between the Registrant and Cantor Fitzgerald & Co.
10.45(12) †	Collaboration Agreement, effective February 21, 2001, by and between Abgenix, Inc. and PSMA Development Company LLC.
10.46 (18) †	Lease, dated December 31, 2015, between the Registrant and WTC TOWER 1 LLC.
10.47(19) †	License Agreement, effective July 30, 2015 between the Registrant and The Johns Hopkins University.
10.49(19)	Employment Offer Letter Agreement between the Registrant and Patrick Fabbio.
10.50(20)	License Agreement, dated April 28, 2016, between PSMA Development Company LLC and Bayer AS.
10.51(21)	Assignment and Assumption Agreement, dated May 6, 2016, between the Registrant and Regeneron Pharmaceuticals, Inc.
10.52(22)	Loan Agreement, dated November 4, 2016, between the Registrant through its wholly-owned subsidiary MNTX Royalties Sub LLC and Healthcare Royalty Partners III, L.P.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP.
31.1	Certification of Mark R. Baker, Chief Executive Officer of the Registrant pursuant to 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Patrick Fabbio, Senior Vice President and Chief Financial Officer of the Registrant pursuant to 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.

32.1	Certification of Mark R. Baker, Chief Executive Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Patrick Fabbio, Senior Vice President and Chief Financial Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document

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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 Registration Statement on Form S-8, Commission File No. 333-120508.
(5) Previously filed in Current Report on Form 8-K filed on June 18, 2014.
(6) Previously filed in Current Report on Form 8-K filed on July 8, 2008.
(7) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
(9) Previously filed in Current Report on Form 8-K filed on November 28, 2012.
(10) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2005.
(11) Previously filed in Quarterly Report on Form 10-Q for the quarter ended June 30, 2006
(12) Previously filed in Amendment No. 2 to Annual Report on Form 10-K/A for the year ended December 31, 2009.
(13) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.
(14) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.
(15) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2013.
(16) Previously filed in Registration Statement on Form S-1, Commission File No. 333-129570 filed by Molecular Insight Pharmaceuticals, Inc.
(17) Previously filed in Registration Statement on Form S-3, Commission File No. 333-227805.
(18) Previously filed in Current Report on Form 8-K filed on January 5, 2016.
(19) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2015.
(20) Previously filed in Current Report on Form 8-K filed on May 4, 2016.
(21) Previously filed in Current Report on Form 8-K filed on May 10, 2016.
(22) Previously filed in Current Report on Form 8-K filed on November 7, 2016.
(23) Previously filed in Current Report on Form 8-K filed on June 14, 2018.
(24) Previously filed in Current Report on Form 8-K filed on May 31, 2018.
(25) Previously filed in Current Report on Form 8-K filed on May 11, 2018.

† Confidential treatment granted as to certain portions omitted and filed separately with the Commission.
‡ Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ MARK R. BAKER
Mark R. Baker
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 14, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Capacity	Date
/s/ PETER J. CROWLEY Peter J. Crowley	Chairman	March 14, 2019
/s/ MARK R. BAKER Mark R. Baker	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2019
/s/ BRADLEY CAMPBELL Bradley Campbell	Director	March 14, 2019
/s/ KAREN J. FERRANTE Karen J. Ferrante, M.D.	Director	March 14, 2019
/s/ MICHAEL D. KISHBAUCH Michael D. Kishbauch	Director	March 14, 2019
/s/ DAVID A. SCHEINBERG David A. Scheinberg, M.D., Ph.D.	Director	March 14, 2019
/s/ NICOLE S. WILLIAMS Nicole S. Williams	Director	March 14, 2019
/s/ PATRICK FABBIO Patrick Fabbio	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2019

Exhibit 21.1

Progenics Pharmaceuticals, Inc.
Subsidiaries

Name	Jurisdiction of Incorporation
Excelsior Life Sciences Ireland Limited	Ireland
Molecular Insight Pharmaceuticals, Inc.	Delaware
Molecular Insight Limited*	England and Wales
Progenics Life Sciences Limited	England and Wales
Progenics Pharmaceuticals Nevada, Inc.	Nevada
PSMA Development Company LLC	Delaware
EXINI Diagnostics AB	Sweden
MNTX Royalties Sub LLC	Delaware

* Subsidiary of Molecular Insight Pharmaceuticals, Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 Nos. 333-227805 and 333-215454) of Progenics Pharmaceuticals, Inc.,
(2) Registration Statements (Form S-8 No. 333-225951) pertaining to the 2018 Performance Incentive Plan of Progenics Pharmaceuticals, Inc., and
(3) Registration Statements (Form S-8 Nos. 333-197071, 333-183511, 333-176204, 333-160389, 333-143670, and 333-124910) pertaining to the 2005 Stock Incentive Plan of Progenics Pharmaceuticals, Inc.

of our reports dated March 14, 2019, with respect to the consolidated financial statements and schedules of Progenics Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Progenics Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Progenics Pharmaceuticals, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 14, 2019

Exhibit 31.1

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a) UNDER THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Mark R. Baker, certify that:

1. I have reviewed this annual report on Form 10-K of Progenics Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's independent registered public accounting firm and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2019

/s/ Mark R. Baker
Mark R. Baker
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a) UNDER THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Patrick Fabbio, certify that:

1. I have reviewed this annual report on Form 10-K of Progenics Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's independent registered public accounting firm and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2019

/s/ Patrick Fabbio
Patrick Fabbio
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT
TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned Chief Executive Officer of Progenics Pharmaceuticals, Inc. (the "Company") does hereby certify as follows:

This annual report on Form 10-K of the Company for the period ended December 31, 2018 and filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Mark R. Baker

Date: March 14, 2019

Mark R. Baker
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Progenics Pharmaceuticals, Inc. and will be retained by Progenics Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT
TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned Chief Financial Officer of Progenics Pharmaceuticals, Inc. (the "Company") does hereby certify as follows:

This annual report on Form 10-K of the Company for the period ended December 31, 2018 and filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Patrick Fabbio

Date: March 14, 2019

Patrick Fabbio
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Progenics Pharmaceuticals, Inc. and will be retained by Progenics Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request