

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, 2019
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
(State or other jurisdiction of incorporation or organization)

13-3379479
(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	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0013 per share	PGNX	The Nasdaq Stock Market

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

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 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 ☐
Non-accelerated filer ☐

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 28, 2019, the last business day of our most recently completed second fiscal quarter, based upon the closing price of the Common Stock on The Nasdaq Stock Market LLC on that date of \$6.17 per share, was \$455,462,193 (1).

- (1) Calculated by excluding all shares that may be deemed to be beneficially owned by executive officers, directors and ten 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 9, 2020, a total of 86,596,633 shares of Common Stock, par value \$.0013 per share, were outstanding.

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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; risks associated with the proposed merger transaction with Lantheus Holdings, Inc. (“Lantheus Holdings”); the unpredictability of the duration and results of regulatory review of New Drug Applications (“NDA”) and Investigational NDA; 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; 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; and the inherent uncertainty of outcomes in intellectual property disputes such as the dispute with University of Heidelberg regarding PSMA-617.

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 Part I, Item 1A of 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 indications or jurisdictions, or that any of our other programs will result in commercial products.

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 enrollment completion of our pivotal phase 3 trial for PyL™ and the positive topline results. Our pipeline includes therapeutic agents designed to precisely target cancer (AZEDRA, 1095 and PSMA TTC), as well as a prostate-specific membrane antigen (“PSMA”) targeted imaging agents for prostate cancer (PyL and 1404).

Highlights of Our Recent Progress:

Corporate

- In January 2019, we appointed Asha Das, M.D. to the newly created role of Chief Medical Officer. Dr. Das brings 15 years of drug development experience, including leading activities related to the approval and launch of Avastin® in multiple indications at Genentech, as well as a decade of clinical practice and academic expertise in neurology and neuro-oncology.
- In accordance with the results of the Velan Consent Solicitation, effective November 8, 2019, the following five directors were elected to the Board to fill the five resulting vacancies on the Board: Gérard Ber, Eric J. Ende, Ann MacDougall, Heinz Mäusli and David W. Mims (collectively, the “New Directors”). The New Directors were elected to serve as directors of the Company until the Company’s 2020 annual meeting of shareholders and until their respective successors are duly elected and qualified. The Board appointed Ms. Ann MacDougall as Interim Chair of the Board.
- On November 11, 2019, Mark. R. Baker tendered his resignation as Chief Executive Officer and as a member of the Board of the Company, which became effective immediately. The Board appointed David W. Mims as Interim Chief Executive Officer.
- On February 20, 2020, we announced the signing of an amended and restated definitive agreement for the proposed merger of Progenics with Lantheus Holdings. The amended agreement reflects the renegotiation of certain of the terms of our original agreement for the proposed merger entered into on October 1, 2019. The combined company would be led by Lantheus Holdings’ Chief Executive Officer, Mary Anne Heino. Ms. Heino will be supported by Chief Financial Officer, Robert J. Marshall Jr., and Chief Operations Officer, John Bolla. The definitive agreement provides that, following the closing, Dr. Gérard Ber and Mr. Heinz Mäusli, currently members of Progenics’ Board of Directors (the “Board”), will be added as members of the Board of Directors of Lantheus Holdings. At the effective time of the merger, each share of Progenics common stock issued and outstanding immediately prior to such time (other than excluded shares and dissenting shares) will be converted into the right to receive (i) 0.31 of a share of Lantheus Holdings common stock and (ii) one non-transferrable contingent value right (“CVR”) per share of Progenics common stock, which will represent the right to receive up to two contingent payments, subject to a cap, upon the achievement of certain milestones subject to the terms of the Contingent Value Rights Agreement (the “CVR Agreement”) to be entered into between Lantheus Holdings and a rights agent reasonable acceptable to Progenics at or immediately prior to the effective time of the merger. The transaction is expected to close early in the second quarter of 2020, subject to approval by Lantheus Holdings and Progenics stockholders, regulatory approvals, and certain other customary closing conditions.

AZEDRA®

- **AZEDRA.** We presented data to the 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). The ICD-10 Coordination and Maintenance Committee is comprised of representatives from the Centers for Medicare and Medicaid Services (CMS). In addition, our pass-through C code was approved and is in place, and our permanent A code was awarded in January 2020. In October 2019, we initiated a global managed access program to provide AZEDRA outside of the U.S. 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 are available at www.AZEDRA.com.
- **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 manufacturing facility for AZEDRA and will also provide manufacturing support for our development stage radiopharmaceuticals, including 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.
- **AZEDRA Life Cycle Management.** We received comments from the U.S. Food and Drug Administration (“FDA”) on our proposed life cycle management program to evaluate AZEDRA in patients with other neuroendocrine tumors (NETs). We are currently on clinical hold until we reach agreement with the FDA on a regulatory path forward. If we reach agreement with the FDA, we anticipate our efforts in this area to commence later this year.

Pipeline Advancement:**PyL (18F-DCFPyL)**

- In December 2018, we entered into an exclusive agreement to develop and commercialize PyL in Europe. PyL is Progenics' PSMA-targeted small molecule PET/CT imaging agent designed to visualize prostate cancer currently in Phase 3 development. Under the terms of the collaboration, Curium was granted an exclusive license to develop and commercialize PyL in Europe. Curium will be responsible for the development, regulatory approvals and commercialization of PyL in the covered territory. Progenics is entitled to royalties on net sales of PyL.
- We completed enrollment in 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 ahead of schedule and reported positive topline results. In December 2019, the CONDOR trial achieved its primary endpoint, with a correct localization rate (CLR) of 84.8% to 87.0% among the three blinded independent readers (the lower bound of the 95% confidence intervals ranging from 77.8% to 80.4%). CLR is based on positive predictive value, defined as the percentage of patients with a one-to-one correspondence between localization of at least one lesion identified on PyL PET/CT and a composite truth standard comprised of histopathology, conventional imaging and/or changes in PSA levels following radiation therapy.

1095

- We advanced our 1095 program and initiated 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 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 for CRPC, and progressed on abiraterone in the U.S. and Canada. The import alert on our clinical supply manufacturer, Centre for Probe Development & Commercialization's ("CPDC"), was lifted in December 2019 and clinical sites and patient enrollment in the U.S. have been initiated.

PSMA AI

- We entered into a transfer agreement with FUJIFILM Toyama Chemical Co, Ltd. ("FUJIFILM") for the rights to the Company's aBSI product in Japan for use under the name BONENAVI®. Under the terms of the agreement, FUJIFILM acquired, by a combination of purchase and license, the Japanese software, source code, supporting data, and all Japanese patents associated with the aBSI product from Progenics for use in Japan. In exchange, Progenics received \$4.0 million in an upfront payment and will receive service fees for aBSI and other AI products over three years in Japan. BONENAVI has been licensed to FUJIFILM for use in Japan since 2011.
- We announced our collaboration with the VA Greater Los Angeles Healthcare System on Progenics' AI research program in July 2019. The collaborative AI research program aims to apply machine learning to medical imaging modalities, enabling standardized, information-driven healthcare practices in prostate cancer. The project is a collaborative effort to validate cutting-edge machine learning tools for improving treatment management of Veterans with prostate cancer. We presented the first data at the Genitourinary Cancers Symposium hosted by the American Society of Clinical Oncology ("ASCO GU") in February 2020 on our deep learning algorithm that can predict whether a patient has metastatic disease using data only from the PET images of the primary prostate tumor.

1404

- We entered into an exclusive agreement under which ROTOP Pharmaka GmbH (“ROTOP”), a Germany-based developer of radiopharmaceuticals for nuclear medicine diagnostics, agreed to develop and commercialize 1404 in Europe. 1404 is Progenics’ PSMA-targeted small molecule SPECT/CT imaging agent labeled with technetium-99m that is designed to visualize prostate cancer. Under the terms of the agreement, ROTOP will receive an exclusive license to and will be responsible for the development, regulatory approvals and commercialization of 1404 in the covered European territory. In exchange, Progenics is eligible for double-digit, tiered royalties based on future sales of 1404 in Europe.

Strategic partnerships:

- RELISTOR® (methylnaltrexone bromide) is licensed to Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch Health Companies Inc. (“Bausch”, which is the predecessor of Valeant Pharmaceuticals International, Inc.). RELISTOR subcutaneous injection and RELISTOR Tablets are approved by the FDA for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. For the year ended December 31, 2019, we recognized \$10.0 million sales milestone under the RELISTOR License Agreement for the achievement of U.S. net sales of RELISTOR in excess of \$100.0 million.
- 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. In May 2019, Bayer dosed the first patient in the Phase 1 trial which triggered a \$2.0 million milestone payment, recorded as part of the license and other revenue.
- Curium has exclusive rights to develop, manufacture and commercialize PyL in Europe. Under the terms of the collaboration, Curium is responsible for the development, regulatory approvals and commercialization of PyL in Europe, and Progenics is entitled to royalties on net sales of PyL. Curium is in discussions with European Medicines Agency (“EMA”) regarding the development path in Europe.
- ROTOP has exclusive rights to develop, manufacture and commercialize 1404 in Europe. Under the terms of the collaboration, ROTOP is responsible for the development, regulatory approvals and commercialization of 1404 in Europe. Under this agreement, Progenics is entitled to double-digit, tiered royalties on future net sales of 1404 in Europe. ROTOP is in discussions with EMA regarding the development path in Europe.
- FUJIFILM had rights to the Company’s aBSI product in Japan for use under the name BONENAVI under a prior agreement. Under the terms of a recently signed transfer agreement, FUJIFILM acquired, by a combination of purchase and license, the Japanese software, source code, supporting data and all Japanese patents associated with the aBSI product from us for their use of aBSI in Japan. In exchange, Progenics received a \$4.0 million upfront payment and is entitled to service fees for the next three years.
- CytoDyn Inc. (“CytoDyn”) acquired leronlimab (PRO 140); the acquisition included a milestone and royalty payment obligations to us. Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including NASH. CytoDyn announced it plans to seek FDA approval for leronlimab in combination therapy for HIV infection and plans to complete the filing of a Biologics License Application (“BLA”) in the first quarter of 2020 for that indication.

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	Progenics
Prostate Cancer Theranostics				
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	Positive Phase 3 topline results	Worldwide (ex. EU, AU, & NZ)	Progenics
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	Discussions with EMA	Europe	Curium
1095 (I 131 1095)	PSMA-targeted small molecule therapeutic for treatment of metastatic prostate cancer	Phase 2	Worldwide	Progenics
PSMA TTC (BAY 2315497)	PSMA-targeted antibody conjugate therapeutic for treatment of metastatic prostate cancer	Phase 1	Worldwide	Bayer
1404	Technetium-99m PSMA-targeted SPECT/CT imaging agent for prostate cancer	Discussions with EMA	Europe	ROTOP
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	Progenics
Automated Bone Scan Index (aBSI)	Automated reading and quantification of bone scans of prostate cancer patients using artificial intelligence and deep learning	Approved in the U.S. and E.U. 510(k) cleared in the U.S. CE marked (E.U. countries)	Worldwide (ex. Japan)	Progenics
Automated Bone Scan Index (BONENAVI)	Automated reading and quantification of bone scans of prostate cancer patients using artificial intelligence and deep learning	Approved	Japan	FUJIFILM
Other Programs				
RELISTOR Subcutaneous Injection (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain or advanced-illness adult patients	Approved	Worldwide	Bausch
RELISTOR Tablets (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain	Approved	U.S.	Bausch
Leronlimab (PRO 140)	HIV Infection	Rolling BLA Submission to FDA	U.S.	CytoDyn

Ultra-Orphan Theranostic:

- **AZEDRA®** (iobenguane I 131) 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 beyond its existing label through the development of new indications.

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, with potential high clinical utility in the detection of recurrent and/or metastatic prostate cancer, as well as staging of high risk disease. We announced positive topline data in the 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.
- **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. We are conducting a Phase 2 clinical trial in combination with enzalutamide in chemotherapy-naïve patients with metastatic castration-resistant prostate cancer (mCRPC) who are PSMA-avid, chemotherapy naïve for CRPC, and progressed on abiraterone, in the U.S. and Canada.
- **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 has exclusive worldwide rights to develop and commercialize products using our PSMA antibody technology in combination with Bayer's alpha-emitting radionuclides. Bayer is conducting a Phase 1 trial of PSMA TTC in patients with metastatic castration-resistant prostate cancer.
- **1404** is a technetium-99m labeled small molecule which binds to PSMA and is used as a SPECT/CT imaging agent to diagnose and detect localized prostate cancer as well as soft tissue and bone metastases. ROTOP has exclusive rights to develop and commercialize 1404 in Europe.

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 performance study of our automated segmentation algorithms with PyL/CT images from our PyL research access initiative. The study demonstrated the efficiency and effectiveness of our fully automated segmentation algorithm of the 49 bones and 12 soft tissue regions of the whole body from PyL-PSMA PET/CT images. The deep learning algorithms demonstrated a Sørensen–Dice score of 0.90 or higher in segmenting anatomical structures in the low dose CT portion of a PyL PET/CT. This work provides automated generation of lesion quantification, localization and staging, therefore leading to highly contextualized assessments of disease burden.
- **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. The Japanese rights to the stand-alone aBSI have been transferred and sold to FUJIFILM under the name BONENAVI®. The cloud based aBSI was cleared by the FDA for clinical use in the U.S. on August 5, 2019.

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 markets outside of the United States. 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 an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including NASH. It is owned by CytoDyn and, pursuant to our agreement with CytoDyn, we have the right to receive certain milestone and royalty payments. CytoDyn announced it plans to seek FDA approval for Leronlimab in combination therapy for HIV infection and plans to complete the filing of a BLA in the first quarter of 2020 for that indication.

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 the purposes of this report, Phase 1 clinical trials evaluate safety, dosing, pharmacokinetics, and mechanisms of action; Phase 2 clinical trials evaluate safety, dosing and efficacy; and Phase 3 clinical trials evaluate larger patient populations for safety and efficacy.

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 detecting metastatic and recurrent prostate cancer, as well as staging of high risk disease. 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 diagnostic performance of PyL to detect prostate cancer in pelvic lymph nodes in patients with high risk locally advanced prostate cancer (Cohort A, N=268) and distant metastases in patients with metastatic or recurrent prostate cancer (Cohort B, N=117). In the trial, the diagnostic performance of PyL in detecting disease in pelvic lymph nodes (Cohort A) showed specificity of 96-99% and sensitivity of 31-42%. The positive predictive value and negative predictive value of pelvic lymph node detection were 78-91% and 81-84%, respectively. In the metastatic or recurrent prostate cancer setting (Cohort B), PyL exhibited sensitivity of 93-99% and PPV of 81-88% in detecting metastatic lesions. Specificity and negative predictive value were not endpoints specified in the protocol for Cohort B as all men in Cohort B were suspected to have disease. Overall, 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 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 $\geq$ 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 2019, we announced the results from a prospective, multicenter, open label pivotal Phase 3 CONDOR trial evaluating the diagnostic performance and clinical impact of PyL in men with biochemical recurrence of prostate cancer and uninformative baseline imaging based on conventional modalities. The study enrolled 208 patients at 14 sites in the United States and Canada. The CONDOR trial achieved its primary endpoint, with a correct localization rate (CLR) of 84.8% to 87.0% among the three blinded independent readers (the lower bound of the 95% confidence intervals ranging from 77.8% to 80.4%). CLR is based on positive predictive value, defined as the percentage of patients with a one-to-one correspondence between localization of at least one lesion identified on PyL PET/CT and a composite truth standard comprised of histopathology, conventional imaging and/or changes in PSA levels following radiation therapy.

Safety results showed PyL was well tolerated and consistent with the Phase 2/3 OSPREY trial results. There was one serious adverse event of hypersensitivity reported in one patient as related to the study drug. The most frequent adverse event reported was headache, which was reported in four patients (1.9% of the trial population).

In addition to our sponsored studies and clinical trial collaborations, the diagnostic performance and clinical utility of PyL are also being 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 $\leq 3+4$ 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 May 2019, we announced the initiation of a multicenter, randomized, controlled Phase 2 trial evaluating the efficacy and safety of 1095 in combination with enzalutamide compared to enzalutamide alone in patients with metastatic castration-resistant prostate cancer (mCRPC) who are PSMA-avid, chemotherapy naïve for CRPC, and progressed on abiraterone. In this trial, PSMA-avidity is determined by utilizing PyL, the Company’s PET imaging agent in clinical development designed to visualize prostate cancer. 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.

As of January 30, 2020, 9 patients have been dosed with I-131-1095+enzalutamide and 2 patients with enzalutamide alone. No dose limiting toxicity (DLT) was observed. There were 22 AEs that were related or possibly related to 1095. There were 8 serious adverse events and none of them were determined to be related or possibly related to the study drug. The most frequent adverse events reported were thrombocytopenia and fatigue. Overall, 1095 has been safe and well tolerated and the independent data monitoring committee has recommended the study continue without modifications.

The trial is expected to randomize approximately 120 patients at 40 sites in the U.S. and Canada. The study's primary endpoint is 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. Key secondary endpoints evaluate radiographic response based on Response Evaluation Criteria In Solid Tumors (RECIST) for soft tissue or PCWG3 for bone, progression free survival (PFS), and overall survival (OS). Patients will be followed for one year after their first treatment for all efficacy endpoints. Survival and safety data will be collected for an additional year.

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 (of which \$8.0 million for the first commercial sale of AZEDRA has already been paid in 2019) 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 \$1.5 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.
- The 2003 exclusive license agreements with The University of Western Ontario for worldwide sublicensable rights to certain intellectual property relates to production methodologies and alternative approaches for preparing AZEDRA. 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 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 \$5.0 million and could receive up to an additional \$44.0 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 in Europe. Curium will be responsible for the development, regulatory approvals and commercialization of PyL in Europe. Curium is in discussions with EMA regarding the development path in Europe. 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 methylaltrexone – 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, a development milestone payment of \$50.0 million for the U.S. marketing approval of an oral formulation of RELISTOR in July 2016 and a \$10.0 million sales milestone for achieving RELISTOR U.S. net sales in excess of \$100.0 million in 2019. We are also eligible to receive up to \$190.0 million of one-time sales milestone payments upon achievement of specified U.S. net sales targets, including:

U.S. Net Sales Levels in any Single Calendar Year	Payment (In thousands)
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
	\$ 190,000

Each sales 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 methylaltrexone, the active ingredient of RELISTOR, which we 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 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.

CytoDyn Agreement

We sold Leronlimab (PRO 140) to CytoDyn in 2012, which sale included milestone and royalty payment obligations to us. Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including NASH. CytoDyn has announced its plans to seek FDA approval for Leronlimab in combination therapy for HIV infection and plans to complete the filing of a BLA in the first quarter of 2020 for that indication.

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 own 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 outside of the United States. The U.S. patent under reexamination was issued with an expiration of 2032. Patent applications are pending relating to automated medical image analysis.

The intellectual property directed to PSMA antibody comprises co-owned and in-licensed patents. Composition-of-matter patents have expirations of 2022 and 2023 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") eight U.S. patents relating to subcutaneous RELISTOR, which have expiration dates ranging from 2024 to 2030, and nine U.S. patents relating to RELISTOR tablet, which have expiration dates ranging from 2029 to 2031. Four Canadian patents (two expiring in 2024, one in 2027 and one in 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 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, PyL and 1095. We 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 manufacturing 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 for necessary redundancy and additional capacity. 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 12 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 BioDelivery Sciences International 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 and chemotherapy are 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.; and Telix Pharmaceuticals. Our principal competitors in the field of prostate cancer imaging agents include Aytu Bioscience Inc., Bracco Diagnostics, Inc., Novartis AG and Telix Pharmaceuticals.

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, 2019, we had 105 full-time employees, 23 of whom hold Ph.D./PharmD degrees and three of whom hold M.D. degrees. At that date, 72 employees were engaged in research and development, medical, regulatory affairs, and manufacturing related activities and 33 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 <https://www.sec.gov>. We also make available on or through our website, free of charge, copies of these reports on <https://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 incorporated by reference into, nor does it form a part of, this report or any other document that we file with the SEC.

Item 1A. Risk Factors

Risks Related to the Pending Merger with Lantheus Holdings

Because the exchange ratio is fixed and will not be adjusted in the event of any changes in either Lantheus Holdings' or our stock price, and because of the uncertainty of the fair market value of, and the ultimate realization on, the CVR, our stockholders cannot be sure of the value of the merger consideration they will receive in the merger.

Upon completion of the merger, each share of our common stock outstanding immediately prior to the completion of the merger (other than shares of our common stock owned by Lantheus Holdings, us or any respective wholly-owned subsidiaries) will be converted into the right to receive (1) 0.31 of a share of Lantheus Holdings common stock without interest and (2) one non-transferrable contingent value right representing the right to receive subject to the CVR cap, such stockholder's pro rata share of aggregate cash payments equal to 40% of U.S. net sales generated by PyL Product (as such term is defined in the CVR Agreement) in calendar years 2022 and 2023 in excess of \$100 million and \$150 million, respectively, as set forth in the CVR Agreement. The exchange ratio will not be adjusted for changes in the market price of either Lantheus Holdings common stock or our common stock between the date the merger agreement was signed and completion of the merger. As a result, changes in the price of Lantheus Holdings common stock prior to the completion of the merger will affect the value of the Lantheus Holdings common stock that our stockholders will receive upon completion of the merger.

The market price of shares of Lantheus Holdings common stock has fluctuated since the date of the announcement of the merger agreement and may continue to change through the date of our special meeting and the date the merger is completed. The actual market value of the Lantheus Holdings common stock received by holders of our common stock may result in an implied value of the merger consideration outside this range. There is also uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized on the CVRs.

Stock price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in Lantheus Holdings' and our respective businesses, operations and prospects, risks inherent in their respective businesses, changes in market assessments of the likelihood that the merger will be completed and/or the value that may be generated by the merger, and changes with respect to expectations regarding the timing of the merger and regulatory considerations. At the time of our special meeting, our stockholders will not know with certainty the value of the shares of Lantheus Holdings common stock that they will receive upon completion of the merger.

If the closing of the proposed merger occurs, our shareholders may not receive any payment on CVRs received as partial consideration for the merger, and the CVRs will not be transferable or registered or listed for trading.

As described above, under the terms of the amended and restated merger agreement, upon completion of the merger, each share of our common stock outstanding immediately prior to the completion of the merger (other than shares of our common stock owned by Lantheus Holdings, us or any respective wholly-owned subsidiaries) will be converted into the right to receive (1) 0.31 of a share of Lantheus Holdings common stock without interest and (2) one non-transferable CVR. Subject to the terms and conditions of the CVR Agreement, each CVR will entitle its holder to receive a pro rata portion of up to two contingent cash payments as follows:

- For the one-year period ending December 31, 2022, Lantheus Holdings will pay an amount equal to 40% of Net Sales relating to PyL Product (as each such term is defined in the CVR Agreement) that exceeds \$100 million.
- For the one-year period ending December 31, 2023, Lantheus Holdings will pay an amount equal to 40% of Net Sales relating to PyL Product that exceeds \$150 million.

In addition, payments under the CVRs are subject to an aggregate cap. The sum of (i) the aggregate amount of payments paid or payable pursuant to the CVR agreement (including any interest on such amounts paid or payable to the rights agent or any CVR holder) and (ii) the amount of any other cash or the fair market value of any property (other than Lantheus Holdings common stock or the CVRs) paid or payable to Progenics stockholders as consideration pursuant to the merger agreement will not (A) exceed 19.9% of the aggregate amount of consideration paid or payable to Progenics stockholders in the merger or (B) constitute an amount the payment of which, in the opinion of nationally recognized tax counsel, would more likely than not prevent the merger from satisfying the requirement of Section 368(a)(2)(E)(ii) of the U.S. Internal Revenue Code.

The CVRs are nontransferable, meaning that they may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of either in whole or in part, other than in certain limited circumstances. The CVRs will not be registered as securities and they will not be listed or traded on any stock exchange in the United States or elsewhere. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in Lantheus Holdings, Merger Sub, Progenics or any of their respective affiliates. Accordingly, the right of any holders of the CVRs to receive any future payment on or derive any value from the CVRs will be contingent solely upon the achievement of the foregoing events within the specified time periods and other terms and conditions of the CVR Agreement, and if these events are not achieved for any reason with such time periods and other terms and conditions, no payments will be made under the CVRs and the CVRs will expire without value.

Lantheus Holdings' obligation to obtain FDA approval for PyL and commercialize it in a manner that maximizes net sales is based on "diligent efforts," which allows for consideration of a variety of factors to determine the efforts Lantheus Holdings is required to take; accordingly, under certain circumstances, Lantheus Holdings may not be required to take certain actions to achieve these goals, which would have an adverse effect on the value, if any, of the CVRs.

From and after the effective time of the merger, Lantheus Holdings has agreed to use "diligent efforts" to obtain FDA approval for and commercially launch the PyL Product as soon as practicable and thereafter commercialize the PyL Product in a manner that maximizes net sales. However, the definition of "diligent efforts" in the CVR Agreement allows for the consideration of a variety of factors in determining the efforts Lantheus Holdings is required to use to achieve these goals, and it does not require Lantheus Holdings to take all possible actions to achieve them. Under the CVR Agreement, the definition of "diligent efforts" requires Lantheus Holdings to use a level of effort, expertise and resources consistent with those efforts, expertise and resources normally used by persons in the medical diagnostics business similar in size and resources to Lantheus Holdings and its affiliates with respect to developing, seeking regulatory approval for and commercializing a product or product candidate that is of similar market potential at a similar stage in its development or product life to the PyL Product.

The U.S. federal income tax treatment of the CVRs is uncertain.

There is no legal authority directly addressing the U.S. federal income tax treatment of the CVRs or the treatment of payments that may be received pursuant to the CVRs. Accordingly, the amount, timing and character of any gain, income or loss with respect to the CVRs are uncertain. Due to the legal and factual uncertainties regarding the tax treatment of the CVRs, U.S. holders are urged to consult their own tax advisors to determine the timing and characterization of income, gain or loss resulting from the receipt of the CVRs and payments pursuant to, sale or other disposition (in certain limited circumstances) of, and the expiration of, the CVRs.

The merger is subject to the expiration or termination of applicable waiting periods and the receipt of approvals, consents or clearances from regulatory authorities that may impose conditions that could have an adverse effect on us or, if not obtained, could prevent completion of the merger.

Before the merger may be completed, any approvals, consents or clearances required in connection with the merger must have been obtained, in each case, under applicable law. Completion of the merger is conditioned upon, among other things, the expiration or termination of the waiting period (and any extension thereof) applicable to the merger under the HSR Act, which, as noted above, has been obtained by grant of early termination of the HSR Act waiting period on October 25, 2019. Notwithstanding the grant of early termination, at any time before or after the merger is completed, the Antitrust Division, the FTC, or U.S. state attorneys general could take action under the antitrust laws in opposition to the merger, including seeking to enjoin completion of the merger, condition completion of the merger upon the divestiture of assets, or impose restrictions on post-merger operations. Any such requirements or restrictions may prevent or delay completion of the merger or may reduce the anticipated benefits of the merger.

The merger is subject to conditions, some or all of which may not be satisfied, or completed on a timely basis, if at all. Failure to complete the merger could have material adverse effects on our business.

The completion of the merger is subject to a number of conditions in addition to the termination or expiration of any applicable waiting period (and any extension thereof) under the HSR Act, including, among other conditions: (i) approval of the merger agreement proposal by our stockholders at our special meeting; (ii) approval of the stock issuance proposal by Lantheus Holdings stockholders at the Lantheus Holdings special meeting; (iii) approval for the listing on the Nasdaq Global Market of the shares of Lantheus Holdings common stock to be issued in the merger and such other shares to be reserved for issuance in connection with the merger; (iv) the absence of any law enacted or order issued by a governmental authority of competent jurisdiction having the effect of making the merger illegal or otherwise prohibiting completion of the merger; (v) the accuracy of the representations and warranties made in the merger agreement by the other party, subject to the applicable materiality standards set forth in the merger agreement; (vi) the absence of any fact, circumstance, condition, development, change, event, occurrence or effect that has had or would reasonably be expected to have, individually or in the aggregate with all other facts, circumstances, conditions, developments, changes, events, occurrences or effects, a material adverse effect on us since the date of the merger agreement; (vii) performance or compliance in all material respects by us with all the agreements and covenants required to be performed by such party under the merger agreement on or prior to the closing date; and (viii) the effectiveness of the registration statement on Form S-4 relating to the merger and no stop order suspending the effectiveness of the registration statement and no proceedings for such purpose initiated or threatened by the SEC.

In addition, the merger agreement contains certain termination rights for both Lantheus Holdings and us, including, among other things, (i) if the merger has not been completed by July 1, 2020, (ii) if the required approval of Lantheus Holdings stockholders or the our stockholders is not obtained, (iii) if the other party willfully breaches its non-solicitation obligations in the merger agreement, (v) if the other party materially breaches its representations, warranties or covenants which breach or failure to perform would result in a failure to satisfy any condition to completion of the merger related to the accuracy of its representations and warranties or the performance of its covenants and agreements, and fails to cure such breach, (vi) if any law or order prohibiting the merger or the stock issuance has become final and non-appealable, or (vii) if the board of directors of the other party changes its recommendation in connection with the merger. If the merger is not completed, our ongoing business may be materially adversely affected and, without realizing any of the benefits that we could have realized had the merger been completed, we will be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on trading prices of Lantheus Holdings common stock and our common stock, and from their respective customers, vendors, regulators and employees;
- we may be required to pay Lantheus Holdings a termination fee of \$18.34 million if the merger agreement is terminated under certain circumstances, and Lantheus Holdings may be required to pay Progenics a termination fee of \$18.34 million if the merger agreement is terminated under certain other circumstances (for more information, see the merger agreement incorporated by reference as an exhibit in this Form 10-K);
- if the merger agreement is terminated and the Lantheus Holdings Board or our Board seeks another business combination, our stockholders cannot be certain that we will be able to find a party willing to enter into a transaction on terms equivalent to or more attractive than the terms agreed to in the merger agreement;
- we will be required to pay certain transaction expenses and other costs incurred in connection with the merger, whether or not the merger is completed, including regulatory filings and legal, accounting, financial advisory, consulting and other advisory expenses, employee benefit-related expenses and filing and printing fees, and, in certain circumstances, certain fees and expenses of Lantheus Holdings in connection with the Lantheus Holdings expense reimbursement (see the merger agreement incorporated by reference as an exhibit in this Form 10-K); and
- matters relating to the merger (including arranging integration planning) will require substantial commitments of time and resources by our management and the expenditure of significant funds in the form of fees and expenses, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us as an independent company.

In addition, if the merger is not completed, we could be subject to litigation related to any failure to complete the merger or related to any enforcement proceeding commenced against us to perform our obligations under the merger agreement. If any such risk materializes, it could adversely impact our ongoing business. Similarly, delays in the completion of the merger could, among other things, result in additional transaction costs, loss of revenue or other negative effects associated with uncertainty about completion of the merger and cause them not to realize some or all of the benefits that they expect to achieve if the merger is successfully completed within its expected timeframe. We cannot assure you that the conditions to the closing of the merger will be satisfied or waived or that the merger will be completed.

In addition, we anticipate it being necessary to obtain additional financing in order to meet our cash requirements if the merger is not consummated. However, there can be no assurances that we will be able to obtain additional capital on acceptable terms and in the amounts necessary to fully fund our current operating expenses or reduced operating expenses reflecting delays or reductions in the scope of our product development programs beyond 2020. These and other circumstances raise substantial doubt about our ability to continue as a going concern if the merger is not consummated. Our independent registered public accounting firm has issued an opinion on our financial statements as of and for the period ended December 31, 2019 included in this Form 10-K, that states that there is substantial doubt about our ability to continue as a going concern and that the financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Uncertainties associated with the merger may cause a loss of management personnel and other key employees, and we may have difficulty attracting and motivating management personnel and other key employees, which could adversely affect the future business and operations of the combined company.

We are dependent on the experience and industry knowledge of their respective management personnel and other key employees to execute their business plans. The combined company's success after the completion of the merger will depend in part upon our ability to attract, motivate and retain key management personnel and other key employees. Prior to completion of the merger, our current and prospective employees may experience uncertainty about their roles within the combined company following the completion of the merger, which may have an adverse effect on our ability to attract, motivate or retain management personnel and other key employees. In addition, no assurance can be given that the combined company will be able to attract, motivate or retain our management personnel and other key employees to the same extent that we have previously been able to attract or retain our own employees.

On February 28, 2020, Mr. Fabbio provided notice to the Progenics Board of his intention to resign as Progenics' Chief Financial Officer, effective March 27, 2020. Mr. Fabbio has agreed to continue providing services to Progenics as a consultant following the effective date of his resignation until the earlier of the effective date of the merger and May 15, 2020 unless terminated by either party as set forth therein.

The merger agreement limits our ability to pursue alternatives to the merger and may discourage other companies from trying to acquire us.

The merger agreement contains a no solicitation covenant that restricts our ability to (i) initiate or solicit or knowingly facilitate, knowingly induce or knowingly encourage any inquiry or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, a takeover proposal, (ii) enter into, continue or otherwise participate in any discussions or negotiations regarding, furnish to any person any information or data with respect to, or cooperate in any way that would otherwise reasonably be expected to lead to, any proposal or offer that constitutes, or would reasonably be expected to lead to, any takeover proposal, (iii) submit to our stockholders for their approval or adoption any takeover proposal, or (iv) agree or publicly announce an intention to take any of the foregoing actions. In the event that we receive a bona fide written takeover proposal, we must promptly communicate the receipt of such proposal and provide copies of all written materials provided, including the terms and conditions of such proposal, to Lantheus Holdings. If, in response to such proposals and subject to certain conditions, we intend to effect a change in recommendation of our Board, we must engage in good faith negotiations with Lantheus Holdings to amend the merger agreement in response to such competing takeover proposal before our Board may make a change in recommendation. The merger agreement further provides that in the event of a termination of the merger agreement under certain specified circumstances, including a termination following a change in recommendation by our Board or a willful breach of the no solicitation provision applicable to it, we may be required to pay the other party a termination fee equal to \$18.34 million. For more information, see the merger agreement incorporated by reference as an exhibit in this Form 10-K.

These provisions could discourage a potential third-party acquirer that might have an interest in acquiring all or a significant portion of our business from considering or proposing that acquisition, even if that party were prepared to pay consideration with a higher per-share value than the currently proposed merger consideration. These provisions might also result in a potential third-party acquirer proposing to pay a lower price in a takeover proposal than it might otherwise have proposed to pay because of the added expense of the termination fee and other fees and expenses that may become payable in certain circumstances.

The shares of Lantheus Holdings common stock to be received by Progenics stockholders upon completion of the merger will have different rights from shares of Progenics common stock.

Upon completion of the merger, our stockholders will no longer be stockholders of Progenics, but will instead become stockholders of Lantheus Holdings, and their rights as Lantheus Holdings stockholders will be governed by the terms of Lantheus Holdings' amended and restated certificate of incorporation (the "Lantheus Holdings certificate of incorporation"), as it may be amended from time to time, and Lantheus Holdings' amended and restated bylaws (the "Lantheus Holdings bylaws"), as they may be amended from time to time. The terms of the Lantheus Holdings certificate of incorporation and the Lantheus Holdings bylaws are in some respects materially different than the terms of our amended and restated certificate of incorporation, as they may be amended from time to time, and our by-laws, as they may be amended from time to time. For more information, see the merger agreement incorporated by reference as an exhibit in this Form 10-K.

We may be a target of securities class action and derivative lawsuits that could result in substantial costs and may delay or prevent the merger from being completed.

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. Even if the lawsuits are without merit, defending against these claims can result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction prohibiting completion of the merger, then that injunction may delay or prevent the merger from being completed, or from being completed within the expected timeframe, which may adversely affect our business, financial position and results of operation. As of the date of filing of this report, we are aware of five pending securities class action lawsuits or derivative lawsuits that have been filed in connection with the merger. One of those lawsuits against Progenics also names Lantheus Holdings or one of its affiliates as a defendant:

- *Johnson v. Progenics Pharmaceuticals, Inc.*, et al., Case No. 19-cv-02183
- *Pill v. Progenics Pharmaceuticals, Inc.*, 19-cv-02268 (D. Del.)
- *Wang v. Progenics Pharmaceuticals, Inc.*, Case No. 1:19-cv-10936 (S.D.N.Y.)
- *Hess v. Progenics Pharmaceuticals, Inc.*, 19-cv-11683 (S.D.N.Y.); and
- *Bernstein IRA v Progenics Pharmaceutical Inc.*, Case No. 19-cv-21200 (D.N.J.)

These cases all principally allege that Progenics and/or various of its officers failed to disclose material information in the Form S-4 filed with the SEC describing the proposed Lantheus Holdings transaction. No plaintiff has yet moved to enjoin the transaction.

In addition, by letter dated October 14, 2019, we received a shareholder demand from the Fireman's Retirement System of St. Louis (the "FRS Demand") under Section 220 of the DGCL to inspect its books and records concerning, among other things, the opposition to the Velan Consent Solicitation and the negotiation and execution of the original merger agreement, and asserting that the Board may have breached its fiduciary obligations. Progenics and FRS executed a confidentiality agreement and negotiated the scope of the production of books and records in response to the FRS Demand, which we have provided. For more information, see the merger agreement incorporated by reference as an exhibit in this Form 10-K.

We are subject to business uncertainties and contractual restrictions while the merger is pending, which could adversely affect our business and operations.

In connection with the pendency of the merger, it is possible that some customers, suppliers and other persons with whom we have a business relationship may delay or defer certain business decisions or might decide to seek to terminate, change or renegotiate their relationships with us as a result of the merger, which could negatively affect our current or the combined company's future, revenues, earnings and cash flows, as well as the market price of our common stock, regardless of whether the merger is completed. Under the terms of the merger agreement, we are subject to certain restrictions on the conduct of our business prior to completing the merger, which could adversely affect our ability to execute certain of our business strategies. Such limitations could adversely affect our business and operations prior to the completion of the merger. Each of the risks described above may be exacerbated by delays or other adverse developments with respect to the completion of the merger.

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. 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.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. The spread of COVID-19 has affected segments of the global economy and may affect our operations by causing a period of business disruption, including the potential interruption of our clinical trial activities and delays or disruptions in the supply of our products and product candidates. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread of COVID-19 globally could also adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. COVID-19, or another infectious disease, could also negatively affect our manufacturing operations, which could result in delays or disruptions in the supply of our product candidates.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business and our results of operation and financial condition.

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 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. In addition, there is a substantial risk that the revenue targets for receiving additional RELISTOR milestone payments will not be met. As a result, there is no assurance that we will realize the potential revenue represented by future RELISTOR milestone payments.

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, readiness of a clinical site to administer a new product and the availability of competitive alternatives that may emerge either during the approval process or after commercial introduction. Frequently, products that have shown promising results in clinical trials suffer significant setbacks even after they are approved for commercial sale.

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

AZEDRA, designated as an Orphan Drug is intended to treat a rare disease with a small patient population. While we have received FDA approval, we are still in discussions with payors regarding 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, there have been several attempts and public announcements by members of the U.S. Congress, President Trump and the Trump administration to repeal the PPACA and replace it with a curtailed system of tax credits and dissolve an expansion of the Medicaid program. For example, Tax Cuts and Jobs Act of 2017 was enacted in 2017, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, and became effective January 1, 2019. 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. For example, until December 2019, the CPDC was subject to an Import Alert by the FDA, which restricted the CPDC's ability to ship products to the U.S. Although the CPDC has since been cleared by the FDA to ship products to the U.S., there can be no guarantee that the CPDC, or any other third-party manufacturer that we may partner with in the future, will not be subject to similar restrictions in the future.

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 owns 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 outside of the United States. The U.S. patent under reexamination was reissued with an expiration of 2032. Applications are pending relating to automated medical image analysis.

With respect to PSMA antibody, currently issued composition-of-matter patents comprising co-owned and in-licensed patents have expirations of 2022 and 2023 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. For example, on November 11, 2019, Mark. R. Baker tendered his resignation as our Chief Executive Officer and as a member of our Board, which was effective immediately. In November 2019, David Mims began serving as our Interim Chief Executive Officer. In addition, on February 28, 2020, Patrick Fabbio provided notice to the Board of his intention to resign as the Company's Chief Financial Officer, effective March 27, 2020. While we intend to find a permanent replacement for the Chief Executive Officer ("CEO") role, we cannot assure you that we will be able to secure such replacement in a timely manner. Even though we are confident in the interim leadership of Mr. Mims, any disruption resulting from Mr. Baker's departure, or any further changes to our key management, commercial and scientific personnel, may be disruptive or cause uncertainty in our business, and may adversely impact our results of operations and financial condition.

Additionally, 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
- the impact of public health epidemics on our business and employees and the global economy, such as the coronavirus, where we directly source materials used for PyL and in our AZEDRA and MIP-1095 manufacturing process; 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; Pfizer, Inc. in collaboration with Astellas Pharma US, Inc.; Aytu Bioscience, Inc.; Bracco Diagnostics, Inc.; Bayer HealthCare Pharmaceuticals Inc. and Telix Pharmaceuticals, 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.

Additionally, the merger agreement contains certain covenants and agreements, which includes, among other others, if requested by Lantheus Holdings, a requirement that we cause our subsidiaries to, take all reasonably necessary actions to (i) facilitate the termination on the closing date of all commitments in respect of the credit facility under the Royalty-Backed Loan, (ii) repay in full on the closing date of the merger all outstanding obligations in respect of the indebtedness under such credit facility, and (iii) release any liens securing such indebtedness and guarantees in connection with such credit facility on the closing date of the merger, in each case pursuant to the delivery to Lantheus Holdings at least three business days prior to the closing of the merger of an executed payoff letter with respect to the credit facility from the applicable agent on behalf of the persons to whom such indebtedness is owed, except that our obligations in this paragraph will be subject to Lantheus Holdings or Merger Sub providing or causing to be provided all funds required to effect all such repayments at or prior to the effective time of the merger. All covenants and agreements are subject to certain exceptions and qualifications as described in the merger agreement, which is filed as an exhibit to this Form 10-K. See above “Risk Factors—Risks Related to the Pending Merger with Lantheus Holdings” for further discussion of risks associated with the pending merger.

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, 2019, our outstanding non-recourse long term debt amounted to \$39.0 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 commercialization 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 2019, 2018 and 2017. 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 product candidates, either alone or with others. Our operations may not be profitable even if our 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 \$6.37 and a low of \$3.42 in 2019, between a high of \$9.42 and a low of \$3.62 in 2018, and between a high of \$11.72 and a low of \$4.60 in 2017. 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, 2019, our directors and executive officers together beneficially owned or controlled approximately 1.6% of our outstanding common shares, including shares currently issuable upon option exercises, and our five largest other stockholders held approximately 50.1%. 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, 2019.

Item 2. Properties

At December 31, 2019, 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, pursuant to the lease expiring December 2021.

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

Paragraph IV Certifications - Mylan

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 (methylaltrexone 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.

Paragraph IV Certification – Actavis

On or about October 27, 2015, January 5, 2016, and January 8, 2016, Progenics, Salix and Wyeth received three separate notifications of a Paragraph IV certification for certain patents for RELISTOR (methylnaltrexone bromide) subcutaneous injection, for certain patents that are listed in the FDA's Orange Book. The certifications resulted from the filing by Actavis LLC of an ANDA with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

District Court Actions

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

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

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

The 2:17-cv-06714-SRC-CLW and 2:17-cv-07206-SRC-CLW were consolidated into a single action in the District of New Jersey (2:17-cv-06714-SRC-CLW). Litigation in 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.

Settlement Agreement - Actavis

On May 25, 2018, Progenics, Bausch, Salix, Wyeth (Progenics, Bausch and Salix, each “Plaintiff” and collectively “Plaintiffs”) and Actavis LLC (“Actavis”) entered into a Settlement and License Agreement (the “Actavis Agreement”) relating to Civil Action No. 2:15-cv-08180 and Civil Action No. 2:17-cv-06714. The Actavis Agreement provides for a full settlement and release by both Plaintiffs and Actavis of all claims that were or could have been asserted in the district court cases and all resulting damages or other remedies. Plaintiffs and Actavis have agreed to and, in fact, filed a stipulated consent judgment and injunction after the execution of the Actavis Agreement. Plaintiffs and Actavis have further acknowledged and agreed that the 30-month stay imposed by the FDA in relation to the approval of Actavis' ANDAs for the Actavis Products (the “Actavis ANDAs”) should be terminated.

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

Federal Circuit Appeal

On May 25, 2018, Mylan filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit (“CAFC”). 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 has concluded. Mylan submitted its opening brief on April 9, 2019. Plaintiffs filed their responsive brief on July 2, 2019. Mylan filed its reply brief on August 6, 2019. Oral argument was held February 4, 2020. We await the decision from the CAFC which we anticipate in a few months.

Paragraph IV Certification - Par

On or about July 15, 2017, Progenics, Salix and Wyeth received notification of a Paragraph IV certification for RELISTOR (methylalntrexone bromide) subcutaneous injection, for certain patents that are listed in the FDA’s Orange Book. The certification resulted from the filing by Par Sterile Products, LLC (“Par Sterile”) of an ANDA with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

District Court Actions

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

Progenics, Salix, Bausch, and Wyeth filed suit against Par Sterile Products, Par Pharmaceutical, and Endo International plc in the Southern District of New York on August 25, 2017 (1:17-cv-06557-PAE) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, 9,180,125, and 9,669,096 based upon Par Sterile Product’s filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR vials before some or all of these patents expire. This action was voluntarily dismissed on November 30, 2017.

Settlement Agreement - Par

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

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

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

RELISTOR Tablets - Actavis

Paragraph IV Certifications

On or about October 24, 2016 and October 24, 2017, Progenics, Salix, Bausch and Wyeth received two separate notifications of a Paragraph IV certification for RELISTOR (methylaltrexone 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, 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, 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). A four day bench trial was held from May 6, 2019 through May 9, 2019. On July 17, 2019, the Court issued an Order finding the asserted claims of U.S. Patent No. 8,524,276 valid and infringed. The Court additionally ordered that the effective date of any approval of Actavis’s ANDA No. 209615 may not be earlier than the expiration date of U.S. Patent No. 8,524,276.

Progenics, Salix, Bausch, and Wyeth filed suit against Actavis, Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. in the District of New Jersey on June 13, 2019 (2:19-cv-13722-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent No. 10,307,417 based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before this patent expires. Litigation in the 2:19-cv-13722-SRC-CLW action is not yet underway.

Federal Circuit Appeal

Actavis filed an appeal of the District Court decision with the CAFC on August 13, 2019. The matter is currently pending on appeal at the Federal Circuit and merits briefing is underway. Actavis's opening brief was filed February 6, 2020.

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. Oral proceedings for EP1615646 are set to occur on September 22, 2020. Oral proceedings for EP2368554 and EP2368553, scheduled for March 9 and March 10, 2020, respectively were cancelled by the Board of Appeals on March 9th due to health concerns. We await a communication from the EPO as to how they intend to proceed.

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

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 patent applications filed worldwide 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 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) 3038996 A1 (EP 14799340.6) and of the Divisional Applications EP 18172716.5, EP 18184296.4, and EP 18203547.7 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. 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; 15/805,900; 16/038,729 and 16/114,988). 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. On November 12, 2019, the University filed a statement with the USPTO to dispute the Confirmation of Ownership filed by MIP.

On February 27, 2019, the German District Court set €416,000 as the amount MIP must deposit with the Court as security in the event of an unfavorable final decision on the merits of the dispute. On February 28, 2019, the Court set a hearing date of August 6, 2019 at which time it held the first oral hearing in the case. The Court considered procedural matters and granted the parties the right to make further submissions. MIP's further submission was timely filed by the October 1, 2019 deadline. The University filed a reply brief on January 31, 2020, and the Court has scheduled a second oral hearing for May 5, 2020.

Third Party Patents

Post-Grant Review of U.S. Patent No. 10,112,974

On July 29, 2019 we filed a petition for post-grant review ("PGR") with the United States Patent and Trademark Office ("USPTO") of U.S. Patent No. 10,112,974 ("the '974 patent"), which is jointly owned by Max-Planck-Gesellschaft zur Foerderung der Wissenschaften and Universitat zu Koln ("the Patent Owners"). Certain claims of the '974 patent recite precursor compounds for preparing PSMA targeting conjugates. In our petition, we allege that such precursor compounds were previously disclosed in other publications, and that certain claims are therefore invalid.

On August 13, 2019, the USPTO mailed a Notice of Filing Date, setting a three (3)-month deadline for the Patent Owners to file a preliminary response. The Patent Owners did not file a response. On January 29, 2020, the Patent Trial & Appeal Board (PTAB) at the USPTO instituted post-grant review of the '974 patent, setting a deadline of April 22, 2020 for the Patent Owners to file a response. A final written decision is expected by January 29, 2021.

Item 4. Mine Safety Disclosures

Not Applicable.

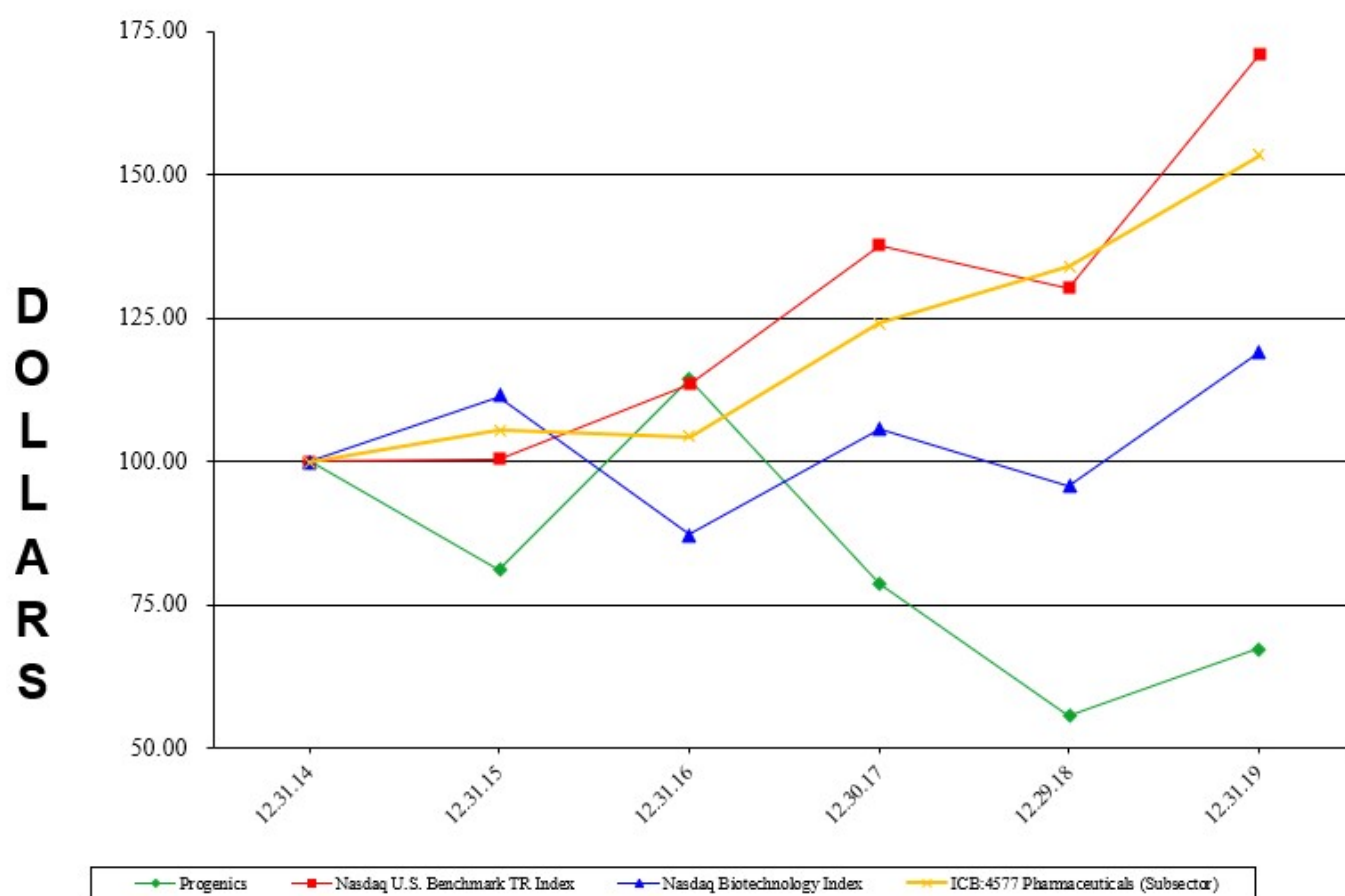
PART II**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Common Stock**

Our common stock is quoted on The Nasdaq Stock Market LLC under the symbol PGNX. On March 9, 2020, there were approximately 64 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 at the market close on December 31, 2014.

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, 2019, 2018, and 2017 and the historical consolidated balance sheet data as of December 31, 2019 and 2018 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, 2016 and 2015 and the historical consolidated balance sheet data as of December 31, 2017, 2016, and 2015 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,				
	2019	2018	2017	2016	2015
(In thousands, except per share data)					
Consolidated Statements of Operations Data:					
Revenue:					
Product sales	\$ 1,559	\$ -	\$ -	\$ -	\$ -
Royalty income	16,970	14,908	10,965	10,295	6,608
License and other revenue	16,457	714	733	59,134	2,068
Total revenue	34,986	15,622	11,698	69,429	8,676
Operating expenses:					
Cost of goods sold	3,168	-	-	-	-
Research and development	49,223	35,147	42,589	37,569	28,196
Selling, general and administrative	47,838	29,431	24,909	23,356	18,184
Intangible impairment charges	-	23,200	-	-	-
Change in contingent consideration liability	916	(5,800)	2,600	(4,600)	1,600
Total operating expenses	101,145	81,978	70,098	56,325	47,980
Operating (loss) income	(66,159)	(66,356)	(58,400)	13,104	(39,304)
Other (expense) income:					
Interest (expense) income and other income, net	(2,376)	(2,933)	(4,285)	(527)	52
Total other (expense) income	(2,376)	(2,933)	(4,285)	(527)	52
(Loss) income before income tax (expense) benefit	(68,535)	(69,289)	(62,685)	12,577	(39,252)
Income tax (expense) benefit	(17)	1,632	11,672	(1,844)	133
Net (loss) income	(68,552)	(67,657)	(51,013)	10,733	(39,119)
Net loss attributable to noncontrolling interests	-	-	-	(73)	(7)
Net (loss) income attributable to Progenics	\$ (68,552)	\$ (67,657)	\$ (51,013)	\$ 10,806	\$ (39,112)
Per share amount on net (loss) income attributable to Progenics:					
Basic	\$ (0.80)	\$ (0.87)	\$ (0.73)	\$ 0.15	\$ (0.56)
Diluted	\$ (0.80)	\$ (0.87)	\$ (0.73)	\$ 0.15	\$ (0.56)

	December 31,				
	2019	2018	2017	2016	2015
(In thousands)					
Consolidated Balance Sheets Data:					
Cash and cash equivalents	\$ 42,049	\$ 137,686	\$ 90,642	\$ 138,909	\$ 74,103
Working capital	41,664	120,683	81,511	131,744	73,556
Total assets	119,470	169,497	145,957	198,986	131,251
Other liabilities - long term	50,849	44,976	67,145	77,867	30,861
Total stockholders' equity	46,553	101,075	63,453	104,762	90,661

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 enrollment completion of our pivotal phase 3 trial for PyL and the positive topline results. Our pipeline includes therapeutic agents designed to precisely target cancer (AZEDRA, 1095 and PSMA TTC), as well as a PSMA targeted imaging agent for prostate cancer (PyL and 1404).

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 advancing our pipeline 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.

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

Recent Developments

On February 20, 2020, we announced the signing of an amended and restated definitive merger agreement for the proposed merger of Progenics with Lantheus Holdings. The amended agreement reflects the renegotiation of certain of the terms of our original agreement for the proposed merger entered into on October 1, 2019. The combined company would be led by Lantheus Holdings' Chief Executive Officer, Mary Anne Heino. Ms. Heino will be supported by Chief Financial Officer, Robert J. Marshall Jr., and Chief Operations Officer, John Bolla. The definitive agreement provides that, following the closing, Dr. Gérard Ber and Mr. Heinz Mäusli, currently members of our Board, will be added as members of the Board of Directors of Lantheus Holdings. The transaction is expected to close early in the second quarter of 2020, subject to approval by Lantheus Holdings and Progenics stockholders, regulatory approvals, and certain other customary closing conditions.

Results of Operations

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

	2019	2018	2017	2019 vs. 2018	2018 vs. 2017
Total revenue	\$ 34,986	\$ 15,622	\$ 11,698	124%	34%
Operating expenses	\$ 101,145	\$ 81,978	\$ 70,098	(23%)	(17%)
Operating loss	\$ (66,159)	\$ (66,356)	\$ (58,400)	0%	(14%)
Net loss	\$ (68,552)	\$ (67,657)	\$ (51,013)	(1%)	(33%)

Revenue

Our sources of revenue during the years indicated below primarily include AZEDRA product sales, royalties, milestones and license fees from Bausch and other collaborators. The following table is a summary of our worldwide revenue (in thousands, except percentages):

Source	2019	2018	2017	2019 vs. 2018	2018 vs. 2017
AZEDRA product sales	\$ 1,559	\$ -	\$ -	N/A	N/A
Royalty income	16,970	14,908	10,965	14%	36%
License and other revenue	16,457	714	733	2205%	(3%)
Total revenue	\$ 34,986	\$ 15,622	\$ 11,698	124%	34%

AZEDRA product sales. We began commercial product sales of AZEDRA in the U.S. in June 2019 (no sales-related deductions or discounts were applicable to date).

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 years ended December 31, 2019 and 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.

	2019	2018	2017	2019 vs. 2018	2018 vs. 2017
U.S.	\$ 110,300	\$ 96,800	\$ 71,100	14%	36%
Outside U.S.	1,300	2,600	2,000	(50%)	30%
Worldwide net sales of RELISTOR	\$ 111,600	\$ 99,400	\$ 73,100	12%	36%

Royalty income increased by \$2.1 million, or 14%, in 2019 compared to 2018 and increased by \$3.9 million, or 36%, in 2018 compared to 2017, due primarily to higher net sales of RELISTOR.

License and other revenue. The license and other revenue increased by \$15.7 million, or 2205% in 2019 compared to 2018, primarily due to recognition of the \$10.0 million RELISTOR sales milestone for the achievement of U.S. net sales over \$100 million, \$2.0 million milestone under the Bayer agreement for initiation of a Phase 1 trial of PSMA TTC and a \$4.0 million upfront payment from FUJIFILM under the aBSI agreement. The license and other revenue remained flat at \$0.7 million in 2018 and 2017.

Operating Expenses

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

Operating Expenses	2019	2018	2017	2019 vs. 2018	2018 vs. 2017
Cost of goods sold	\$ 3,168	\$ -	\$ -	N/A	N/A
Research and development	49,223	35,147	42,589	(40%)	17%
Selling, general and administrative	47,838	29,431	24,909	(63%)	(18%)
Intangible impairment charge	-	23,200	-	100%	N/A
Change in contingent consideration liability	916	(5,800)	2,600	(116%)	323%
Total operating expenses	\$ 101,145	\$ 81,978	\$ 70,098	(23%)	(17%)

Cost of Goods Sold ("COGS")

COGS include cost of direct materials and labor and indirect expenses used in the manufacturing of AZEDRA beginning with the first commercial sale in June 2019.

Research and Development ("R&D")

We do not track fully burdened R&D costs separately for each of our product candidates. We review our R&D expenses by focusing on external and internal development costs. External development costs consist of costs associated with our clinical trials, including pharmaceutical development and investments in manufacturing. 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,		
	2019	2018	2017
External Costs			
PyL	\$ 14,647	\$ 9,053	\$ 8,633
AZEDRA	8,886	5,982	11,394
1095	6,977	988	671
PSMA AI	1,173	1,241	589
1404	423	2,645	7,428
RELISTOR	8	48	1,126
Other	4,072	2,685	2,674
Total External Costs	\$ 36,186	\$ 22,642	\$ 32,515
Internal Costs	13,037	12,505	10,074
Total R&D Costs	\$ 49,223	\$ 35,147	\$ 42,589

R&D expenses increased by \$14.1 million, or 40%, in 2019 compared to 2018, primarily due to higher costs associated with the transition of the AZEDRA manufacturing site, initiatives to increase production capacity and provide redundancy for iodine-based products, AZEDRA and 1095, higher clinical trial and contract manufacturing costs for clinical trial materials for 1095 and PyL, partially offset by lower clinical trial costs for 1404. 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.

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

SG&A expenses increased by \$18.4 million, or 63%, in 2019 compared to 2018, primarily due to legal and advisory fees of \$8.9 million associated with the contested election at our 2019 annual meeting of shareholders and the consent solicitation campaign; legal and advisory fees associated with the acquisition agreement with Lantheus Holdings of \$3.4 million in 2019; and higher PSMA-617 litigation costs of \$2.8 million. 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.

Intangible Impairment Charge

The completion of the 1404 Phase 3 trial in 2018, 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 contingent consideration liability increased by \$0.9 million during the year ended December 31, 2019, primarily due to an increase in the AZEDRA sales forecasts associated with a potential study to expand the label for AZEDRA. 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 2 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.

Other (Expense) Income

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

	2019	2018	2017	2019 vs. 2018	2018 vs. 2017
Interest (expense) income, net	\$ (2,443)	\$ (2,912)	\$ (4,038)	16%	28%
Other (expense) income, net	67	(21)	(247)	419%	91%
Other (expense) income	\$ (2,376)	\$ (2,933)	\$ (4,285)	19%	32%

Total other (expense) income, net decreased by \$0.6 million, or 19% in 2019 compared to 2018, primarily attributable to lower interest expense resulting from lower debt balance in 2019. 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 2018.

Income Tax Benefit (Expense)

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

	2019	2018	2017
Income tax benefit (expense)	\$ (17)	\$ 1,632	\$ 11,672
Effective tax rate	-0.03%	2.4%	18.6%

We account for income taxes using the liability method in accordance with the Accounting Standards Codification (“ASC”) Topic 740, *Income Taxes*. Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

In 2019, we recorded an income tax expense of approximately \$0.02 million as a result of the change in the temporary difference between carrying amounts of in process research and development assets for financial reporting purposes and the amounts used for income tax purposes. Our effective tax rate for 2019 was -0.03%.

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%.

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%.

Liquidity and Capital Resources

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

	2019	2018	2017
Cash and cash equivalents	\$ 42,049	\$ 137,686	\$ 90,642
Accounts receivable, net	\$ 15,976	\$ 3,803	\$ 3,972
Total assets	\$ 119,470	\$ 169,497	\$ 145,957
Working capital	\$ 41,664	\$ 120,683	\$ 81,511

Our current principal sources of revenue are AZEDRA sales, royalties, and development and commercial milestones. Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2019, we had cash and cash equivalents of approximately \$42.0 million, a decrease of \$95.7 million from \$137.7 million at December 31, 2018, reflecting primarily cash used for operating expenses, for the acquisition, transition and start-up costs of the Somerset site for the manufacturing of AZEDRA and capital expenditures at the Somerset site and contract manufacturing organizations related to additional iodine manufacturing capacity.

On February 20, 2020, we announced the signing of an amended and restated definitive merger agreement for the proposed merger of Progenics with Lantheus Holdings. The amended agreement reflects the renegotiation of certain of the terms of our original agreement for the proposed merger entered into on October 1, 2019.

While we strongly believe the Lantheus Holdings transaction represents the best path forward for the Company, if the Lantheus Holdings agreement is not ultimately consummated, we will operate on a stand-alone basis and will continue to have significant cash requirements to support product development activities, commercialization of AZEDRA and pre-launch activities for PyL. The amount and timing of our cash requirements will depend on the progress and success of our clinical development programs, regulatory and market acceptance, and the resources we devote to research and commercialization activities. Additionally, under specified circumstances, we may be required to pay Lantheus Holdings a termination fee of \$18.34 million or reimburse Lantheus Holdings up to \$5.2 million of its reasonable and out-of-pocket costs and expenses incurred in connection with the agreement.

Consistent with regular practice for a growth-stage pharmaceutical or biotechnology company, and as we have done in the past, we anticipate obtaining additional financing, in order to meet our cash requirements if the Lantheus Holdings agreement is not consummated and we believe we have a viable strategy to do so. However, there can be no assurances that we will be able to obtain additional capital on acceptable terms and in the amounts necessary to fully fund our current operating expenses or reduced operating expenses reflecting delays or reductions in the scope of our product development programs beyond one year from the date this annual report is issued. As such, we believe there is substantial doubt regarding our ability to continue as a going concern within one year after the date this Annual Report on Form 10-K is filed with the SEC. The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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):

	2019	2018	2017
Net cash used in operating activities	\$ (74,698)	\$ (46,752)	\$ (54,107)
Net cash used in investing activities	\$ (15,508)	\$ (817)	\$ (232)
Net cash (used in) provided by financing activities	\$ (3,901)	\$ 94,717	\$ 5,510

Operating Activities

Net cash used in operating activities during 2019, 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.

Investing Activities

Net cash used in investing activities was primarily related to the acquisition of AZEDRA manufacturing assets in Somerset, New Jersey and capital expenditures to increase production capacity and provide redundancy for iodine-based products.

Financing Activities

Net cash used in financing activities during the year ended December 31, 2019 was primarily attributable to repayment of debt under the Royalty-Backed Loan with HealthCare Royalty Partners III, L.P, partially offset by proceeds received from exercise of stock options. 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, 2019 for future payments under these agreements (in millions):

	Total	Payments Due by Period (1)			
		Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
Operating leases	\$ 25.4	\$ 2.0	\$ 4.3	\$ 4.6	\$ 14.5
Fixed payments under license agreements	1.3	0.2	0.4	0.4	0.3
Total	\$ 26.7	\$ 2.2	\$ 4.7	\$ 5.0	\$ 14.8

(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) \$90.5 million in contingent milestone payments under our license agreements; (ii) \$85.0 million in payments to the former stockholders of MIP, contingent upon achieving specified commercialization events or sales targets; and (iii) \$47.0 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.

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 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.

Leases. We determine whether an arrangement is or contains a lease at its inception. We recognize lease liabilities based on the present value of the minimum lease payments not yet paid by using the lease term and discount rate determined at lease commencement. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate to determine the present value of our lease payments. Our leases may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. We recognize the operating right-of-use ("ROU") lease assets at amounts equal to the lease liability adjusted for prepaid or accrued rent, remaining balance of any lease incentives and unamortized initial direct costs.

The operating lease liabilities are reported as current and noncurrent liabilities and the related operating ROU lease assets are reported as noncurrent assets on our condensed consolidated balance sheets. Lease expense for our operating leases is calculated on a straight-line basis over the lease term and is reported in research and development and selling, general and administrative expenses on our condensed consolidated statements of operations. We do not recognize a lease liability or ROU lease assets for leases whose lease terms, at commencement, are twelve months or less, or for leases which are below the established capitalization threshold.

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 \$35.8 million at December 31, 2019. 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, 2019, 2018, and 2017, 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, 2019 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, 2019.

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, 2019 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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated March 13, 2020 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 13, 2020

Item 9B. Other Information

None.

PART III**Item 10. Directors, Executive Officers and Corporate Governance****EXECUTIVE OFFICERS AND DIRECTORS**

Information concerning our executive officers and members of our Board is set forth below. There are no family relationships between any of our directors and executive officers. None of the organizations identified below with which an officer has previously been employed or associated is a parent, subsidiary or affiliate of the Company.

Name	Position(s) with the Company
David W. Mims	Interim CEO and Director
Asha Das	Chief Medical Officer
Patrick Fabbio	Executive Vice President and Chief Financial Officer (“CFO”)
Benedict Osorio	Chief Operating Officer (“COO”)
Bryce Tenbarge	Senior Vice President, Commercial
Vivien Wong	Executive Vice President, Development
Gérard Ber	Director
Bradley L. Campbell	Director
Eric J. Ende	Director
Karen J. Ferrante	Director
Ann MacDougall	Director
Heinz Mäusli	Director

Executive Officers

Mr. Mims’ biographical information is set forth below under the heading “Directors.”

Dr. Das, 55, joined us in January 2019 as Chief Medical Officer. Dr. Das most recently served as Tocagen Inc.’s Chief Medical Officer, where she led the development of the company’s cancer-selective gene therapy platform. From April 2008 to April 2015, Dr. Das served at Genentech Inc., a member of the Roche Group, in positions of increasing responsibility, initially as Associate Medical Director and ultimately as Group Medical Director. She was responsible for leading activities related to the approval and launch of Avastin in recurrent glioblastoma, expansion into platinum-resistant ovarian cancer and metastatic cervical cancer as well as clinical activities related to TECENTRIQ®. From 2005 to 2008, Dr. Das served as Associate Medical Director at Eisai Inc., a pharmaceutical company, where she focused on clinical activities related to the oncology therapeutics HALAVEN® and LENVIMA™. Prior to that, Dr. Das was head of the neuro-oncology program at Cedars-Sinai Medical Center.

Dr. Das is certified in neurology by the American Board of Psychiatry and Neurology and in the sub-specialty of neuro-oncology by the United Council for Neurologic Subspecialties and previously served as a clinical fellow in neuro-oncology at Massachusetts General Hospital. Dr. Das completed her residency in neurology at Cornell Medical Center and has held academic appointments at the University of California, Los Angeles; University of California, San Francisco; and National University of Singapore. Dr. Das obtained her medical degree and bachelor’s degree from Cornell University.

Mr. Fabbio, 52, joined us in November 2015 as Senior Vice President and CFO. Prior to joining us, he was Chief Financial Officer of electroCore, a privately-held bioelectric medicine healthcare company, and Vice President, Finance for NPS Pharmaceuticals, Inc., a publicly traded, global rare disease company. Mr. Fabbio has more than 20 years of financial leadership experience in both public and private life science and pharmaceutical companies including: Vice President, Finance, Catalent Pharma Solutions; Chief Financial Officer of Ikano Therapeutics; senior corporate finance, commercial, and transactional roles at Sanofi; and Corporate Controller for Biomatrix Inc., a publicly traded biotechnology company that was acquired by Genzyme. He also joined the board of directors of BeyondSpring Inc. on January 1, 2018. He graduated from Pace University with a B.B.A. in Accounting and from the Stern School of Business at New York University with an M.B.A. in Finance. He received his certified public accountant license in New Jersey. Mr. Fabbio will resign as our CFO effective March 27, 2020.

Mr. Osorio, 63, initially joined us in July 2005 until October 2012 and returned in February 2018, and is currently our COO. He has over three decades of experience in pharmaceutical quality control and quality assurance, including service as Vice President, Quality Assurance at Acorda Therapeutics, Vice President, Quality Assurance at Achillion Pharmaceuticals, Vice President, Quality Operations North America at Valeant Pharmaceuticals, Global Head of Quality for Braeburn Pharmaceuticals, Senior Consultant at Complya Consulting, Vice President and Senior Vice President, Quality at Progenics Pharmaceuticals, Director and Senior Director at Forest Laboratories, various positions of increasing responsibility with The PF Laboratories (a subsidiary of Purdue Pharma), ultimately as Executive Director, Quality Assurance and analytical chemist with Berlex Laboratories. He earned both an M.B.A. and an M.S. in chemistry from Seton Hall University and a B.S. in forensic science from John Jay College of Criminal Justice.

Mr. Tenbarge, 47, joined us in August 2016 and currently serves as Senior Vice President, Commercial. Prior to joining us, he was Vice President of Marketing and Commercialization at Celldex Therapeutics, a publicly-traded biotechnology company. Mr. Tenbarge has more than 15 years of commercial leadership experience with highly specialized products including: Senior Director of Global Oncology Marketing at Teva Pharmaceuticals and a variety of roles of increasing responsibility at Bristol-Myers Squibb Company in professional and payer marketing, market research and business intelligence. Mr. Tenbarge started his career as a commodity trader at Archer Daniels Midland in Chicago prior to receiving his M.B.A. from The Ross School of Business at the University of Michigan.

Dr. Wong, 63, joined us in September 2007 and currently serves as Executive Vice President, Development. For three years prior to joining us, Dr. Wong was Principal at Theritas Pharmaceutical Consultants. From 1989 to 2004, she held positions of increasing responsibility in preclinical development and pharmacology at Emisphere Technologies, Vivoquest, and Regeneron Pharmaceuticals. Dr. Wong has led the development and recent approval of AZEDRA® by FDA, and played a key role in the approvals of Relistor® Subcutaneous Injection and Relistor® Tablets. Her pioneer research in pharmacology had paved the path for the development of Arcalyst®, Eylea®, Zaltrap®, Kevzara®, and Dupixent®. Dr. Wong has been a co-author on over 30 scientific articles for peer-reviewed journals. She received a B.Sc. in biology from the Mississippi University for Women, a Ph.D. in anatomy and neurobiology from the University of Maryland School of Medicine, and completed a postdoctoral fellowship in neurology at the Albert Einstein College of Medicine.

Directors

Dr. Ber, 62, joined our Board in November 2019. In 2002, Dr. Ber co-founded Advanced Accelerator Applications S.A. (“AAA”), and was its Chief Operating Officer from 2002 to 2018, when it was sold to Novartis AG for nearly \$4 billion. Dr. Ber grew AAA from a start-up to a global leader in nuclear medicine and was member of its board of directors from 2002 to 2014, when AAA listed on The Nasdaq Global Select Market. Dr. Ber was responsible for all aspects of US and Worldwide commercial efforts, drug development, supply chain, and business development activities at AAA, including the successful launch of Lutathera® for the treatment of gastropancreatic neuroendocrine tumors and various diagnostic radiopharmaceutical agents. Prior to joining AAA, Dr. Ber served as the Director of OM Pharma’s Western European group from 2000 to 2002, the Director General and Director of Marketing and Commerce for CIS Medipro from 1994 to 2000, and in various management roles at CIS Bio International from 1984 to 1994. Dr. Ber serves as a Board member of Y-mAbs, a Nasdaq-listed late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. He received his PhD degree in Pharmacy from the Scientific and Medical University of Grenoble and a degree in marketing and international commerce from the Institut de Pharmacie Industrielle de Paris in Paris, France.

Dr. Ber brings to the Board more than 30 years’ experience in molecular nuclear medicine and extensive experience in pharmaceutical development and commercialization.

Mr. Campbell, 44, joined our Board in June 2016. He has over 15 years of experience in the orphan drug industry and is currently serving as President and Chief Operating Officer as well as a member of the Board of Directors of Amicus Therapeutics, Inc. (“Amicus”) (Nasdaq: FOLD). In this capacity, he leads the global organization responsible for the commercialization of Galafold for the treatment of Fabry Disease. He also oversees the Technical Operations, Market Access, and Program Management functions. Prior to Amicus, Mr. Campbell spent time in various commercial and business development roles at Genzyme and Bristol-Myers Squibb and as a financial strategy consultant for Marakon Associates. He is also a past President of the National Tay-Sachs and Allied Diseases Association Board of Directors where he currently serves on their Corporate Advisory Council. Mr. Campbell received a B.A. in Public Policy from Duke University and an M.B.A. from Harvard Business School.

Mr. Campbell’s qualifications for serving as a member of our Board include his extensive experience in the pharmaceutical industry in the areas of corporate strategy, commercial operations and planning, business development and sales and marketing.

Dr. Ende, 51, joined our Board in November 2019. Since 2009, Dr. Ende has served as President of Ende BioMedical Consulting Group (“Ende BioMed”). Ende BioMed is focused on helping life sciences companies raise capital, identify licensing partners and acquirers, and optimizing corporate structure. In addition, it analyzes both private and public investment opportunities for clients within the life sciences industry. Dr. Ende also helps activist investors gain seats on company boards.

Dr. Ende was a Director on Genzyme Corporations’ board of directors from 2010 to 2011, until it was acquired by Sanofi-Aventis in 2011. During his tenure on Genzyme’s board, he was a member of the Audit and Risk Management Committees. Dr. Ende is currently on the board of directors of Matinas BioPharma, where he is the chairman of the compensation committee and is serving on the Audit as well as the nomination & governance committees. Dr. Ende is also on the board of directors of Avadel plc, where he is the chairman of the nomination & corporate governance committee and is serving on the audit and compensation committees. Dr. Ende is also on the Technology Transfer Committee of Mount Sinai Innovation Partners. He also served as the chairman of the unsecured creditor’s committee overseeing Egenix Inc.’s bankruptcy and on the subsequent liquidating trust committee.

From 2002 through 2008, Dr. Ende was the senior biotechnology analyst at Merrill Lynch. From 2000 to 2002, Dr. Ende was the senior biotechnology analyst at Banc of America Securities. From 1997 to 2000, he was a biotechnology analyst at Lehman Brothers. During Dr. Ende’s career as a biotechnology analyst, he was named to Institutional Investor’s All-America Equity Research Team six times as well as to The Greenwich Survey list of top analysts. He was also named Top Stock Picker by The Street.com and Best Earnings Estimator by Forbes.com.

Dr. Ende received an M.B.A. in Finance & Accounting from NYU – Stern Business School in 1997, an MD from Mount Sinai School of Medicine in 1994, and a BS in Biology and Psychology from Emory University in 1990.

Dr. Ende brings to our Board insight into the medical field as well as consulting experience within the life sciences industry.

Dr. Ferrante, 62, joined our Board in January 2014. From April 2014 to August 2016, she was the head of Research and Development and Chief Medical Officer of Tokai Pharmaceuticals, Inc., a publicly traded biopharmaceutical company developing treatments for prostate cancer and other hormonally driven diseases. From 2007 to July 2013, Dr. Ferrante held senior positions at Millennium Pharmaceuticals, Inc. and its parent company, Takeda Pharmaceutical Company Limited, including Chief Medical Officer and most recently as Oncology Therapeutic Area Head and Cambridge USA Site Head from May 2013 to July 2013. From 1999 to 2007, she held positions of increasing responsibility at Pfizer Global Research & Development, culminating as Vice President, Oncology Development. She began her career in the pharmaceutical industry in 1995 as Associate Director of Clinical Oncology at Bristol-Myers Squibb Company. Prior to that, she was at the New England Deaconess Hospital in Boston (Beth Israel Deaconess), where she completed her internship and residency in internal medicine followed by her fellowship in hematology and oncology. While at Beth Israel Deaconess, she served as Instructor, Clinical Instructor and Clinical Fellow in Medicine at the Harvard Medical School. Dr. Ferrante serves on the Boards of MacroGenics, Inc., a publicly traded clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, autoimmune disorders and infectious diseases; Hutchinson China MediTech Limited, a publicly traded innovative biopharmaceutical company which researches, develops, manufactures and sells pharmaceuticals and health care products; and, since February 2018, Unum Therapeutics Inc., a publicly traded clinical-stage biopharmaceutical company focused on the development and commercialization of novel immunotherapy products. Dr. Ferrante also served as a director of Baxalta Inc., a publicly traded global biopharmaceutical company until its acquisition by Shire Pharmaceuticals in June 2016. She holds a B.S. in Chemistry and Biology from Providence College and an M.D. from Georgetown University; she has also been an author of a number of papers in the oncology field, is an active participant in academic and professional associations and symposia, and holds several patents.

Dr. Ferrante’s more than two decades’ experience working with major biotechnology and pharmaceutical companies and leading their efforts in oncology research and development and clinical activities, together with her knowledge in our principal focus of operations, adds broad and significant insight into our developmental and clinical efforts for the perspective of our Board.

Ms. MacDougall, 66, joined our Board in November 2019. Ms. MacDougall is an experienced executive, attorney and impact investor. She co-founded the Dunollie Fund, where she has served as chief executive officer since January 2018. Ms. MacDougall has also served since November 2017 as a Senior Advisor at Encore.org, a national organization building a movement for individuals developing second careers in public or non-profit service, where she also served as President from January 2014 through October 2017. From 2007 to 2012, she was chief operating officer of Acumen, a global investment fund focused on goods and services for low-income customers. From 1990 to 2007, she had a legal and management career at PriceWaterhouseCoopers LLP, including as General Counsel/Management Committee Member of the U.S. firm and Global Deputy General Counsel based in Paris. Ms. MacDougall sits on the board of Opiant Pharmaceuticals, Inc. where she chairs the Compensation Committee and is a member of the Governance and Nominations Committee, and also on the board of Atmos XR, a technology company. She earned her BA at Tufts University, her J.D. at Brooklyn Law School and was a fellow at the Harvard Advanced Leadership Initiative.

With her significant corporate, governance and legal expertise, Ms. MacDougall provides a valuable perspective to our Board.

Mr. Mäusli, 57, joined our Board in November 2019. He serves on the board of directors of Inventiva S.A., a clinical-stage biopharmaceutical company, listed on Euronext Paris. He served as AAA's Chief Financial Officer from 2003 until July 2018. He also was AAA's general counsel from 2003 to 2015 and a member of its board of directors from 2008 to 2014. Prior to AAA, he was a management consultant. Mr. Mäusli received a lic.oec. from University of St.Gallen in Switzerland and an M.B.A. from Columbia Business School.

With over 15 years of experience in molecular nuclear medicine, Mr. Mäusli adds significant expertise to our Board.

Mr. Mims, 57, Interim CEO, joined our Board in November 2019. Mr. Mims has served as a member of the board of directors at each of Guideway Care, a healthcare company that provides technology-enabled care guidance, since May 2017 and SouthPoint Bank, a community banking institution, since August 2015. Previously, Mr. Mims served as President at U.S. Specialty Pharmaceuticals for Aptalis Pharma Inc. ("Aptalis") (f/k/a Axcan Pharma Inc.), a privately held pharmaceutical company, from May 2011 until May 2014, shortly after it was acquired by Forest Laboratories, Inc. (formerly NYSE: FRX) and where he managed over 200 employees. Mr. Mims similarly served as President of U.S. Specialty Pharmaceuticals at Axcan Intermediate Holdings Inc., the parent company of Axcan Pharma Inc. (formerly TSE: AXP and Nasdaq: AXCA), from February 2008 until May 2014 and as a member on its board from 2000 to 2007. Mr. Mims began working at Axcan Pharma Inc. as Executive Vice President and Chief Operating Officer in 2000 after the company acquired Scandipharm, Inc., a privately held pharmaceutical company, which Mr. Mims helped found and for which he served as Vice President, Chief Operating Officer and Chief Financial Officer, from 1991 until 1998. Currently, Mr. Mims serves as a member of the American Institute of Certified Public Accountants and Alabama Society of Certified Public Accountants. Previously, Mr. Mims served as a director of the University of Alabama at Birmingham Research Foundation. Mr. Mims is a licensed CPA (inactive). Mr. Mims received his B.S. in accounting from Auburn University.

Given Mr. Mims' extensive career as a pharmaceutical executive, as well as experience in leading multiple commercial organizations, Mr. Mims is well-positioned to serve as a director on our Board and as Interim CEO.

CORPORATE GOVERNANCE

Code of Business Ethics and Conduct

We have a Code of Business Ethics and Conduct (the "Code") which is applicable to all of our directors, employees and consultants. The Code meets the criteria for a "code of ethics" under the SEC rules and "code of conduct" under the Nasdaq Marketplace rules. The Code is described in more detail under *Item 13. Certain Relationships and Related Transactions*, below, and is available on our website at www.progenics.com. Waivers from, and amendments to, the Code that apply to our directors, executive officers or persons performing similar functions will be timely posted in the Investors—Corporate Governance section of our website at www.progenics.com to the extent required by applicable rules of the SEC or the Nasdaq Stock Market LLC.

Audit Committee

We have a standing Audit Committee of the Board. The Audit Committee reviews our quarterly and annual financial statements and the reporting documents in which they are submitted to the SEC, consults with our independent auditors and examines and considers other matters relating to the audit of our financial statements and our financial condition and affairs generally, including the selection and retention of our independent auditors. It is responsible for oversight of our outsourced internal audit provider, which reports directly to it, oversees the work of management to identify, assess, and monitor risk, and liaises with management and the Board in risk mitigation efforts. As of November 8, 2019, our Audit Committee consists of Mr. Mäusli, Mr. Campbell and Dr. Ende. Mr. Mäusli, Chair of the Committee, is an "audit committee financial expert" as such term is defined in SEC rules and an "independent director" as such term is defined in Nasdaq Marketplace rules. See *Director Independence* under *Item 13. Certain Relationships and Related Transactions* for information about the independence of each of the other members of the Audit Committee.

Section 16(a) Beneficial Ownership Reporting Compliance

Based solely on our review of the reports under Section 16(a) of the Exchange Act and representations furnished to us with respect to the last fiscal year, we believe that each of the persons required to file such reports timely complied with all applicable filing requirements during 2019. We continue to monitor the effectiveness of our policies and procedures designed to ensure compliance with Section 16 reporting requirements.

Item 11. Executive Compensation

Compensation Discussion and Analysis

We are an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer. 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 agents for prostate cancer (PyL and 1404). We compete with biopharmaceutical companies of all sizes to attract employees with the skills and expertise necessary to develop and commercialize drugs and achieve our objectives. Since the funds we can use for compensation are limited, we have worked to develop a compensation program that allows us to attract and retain talented individuals with the essential experience and skills we need at the executive level while being mindful of our limited resources. This Compensation Discussion and Analysis outlines, among other things, our compensation philosophy, objectives and processes as they relate to our NEOs in 2019: David W. Mims, our Interim CEO; Patrick Fabbio, our CFO; Benedict Osorio, our COO; Asha Das, our Chief Medical Officer; and Vivien Wong, our Executive Vice President, Development. Mark R. Baker, our former CEO, is also a NEO for 2019 under applicable SEC rules. Mr. Fabbio has announced that he will resign as our CFO, effective March 27, 2020.

Compensation Summary. As a development stage pharmaceutical company, our timeline for performance achievement is very long and depends strongly on our progress against development and commercialization goals, while managing expenses and retaining top talent. Furthermore, our stock price is a meaningful measure of our progress against these goals. As such, our executive compensation program is designed around these factors. Our program combines base salary with an annual bonus opportunity and long-term equity incentives, primarily in the form of stock options. We strive to conserve cash resources by setting base salaries and total cash compensation at what we deem an appropriate level in view of market compensation data in our industry and other factors as discussed below, while providing meaningful long-term equity opportunities for our executives.

Pay Element	Description	2019 Outcome
Base Salary	Fixed Annual Cash Compensation	Annual salary increases for the CEO and other NEOs as described below.
Annual Incentive	Variable Annual Cash Compensation Company Performance: 100% Weighting for CEO / 75% Weighting for other NEOs - Includes three pipeline goals, one commercialization goal, and one financial goal Individual Performance: 0% weighting for CEO / 25% Weighting for other NEOs	CEO's 2019 Payout: None Other NEO 2019 Payouts: 80.0% to 82.5% of target
Long-Term Incentive	Variable Long-Term Equity Compensation 100% Stock Options Vest Ratably Annually over 3 Years	NEOs' 2019 stock option grant date fair value set 35.5% lower than their 2018 awards

Performance Overview. We believe that the total compensation awarded to our NEOs for 2019 appropriately reflects the performance of the executive and the Company and is consistent with our compensation philosophy. We made significant progress in achieving strategic objectives and program development in 2019.

Lantheus Holdings Merger

- In October 2019, we announced the signing of a definitive agreement in which Lantheus Holdings will acquire Progenics, offering a significant upside opportunity to the combined shareholders from a diversified, high growth portfolio with the potential for strong, growing profits. The combination of Lantheus Holdings and Progenics forms a leader in precision diagnostics and radiopharmaceutical therapeutics. The combined company would be led by Lantheus Holdings' Chief Executive Officer, Mary Anne Heino. Ms. Heino will be supported by Chief Financial Officer, Robert J. Marshall Jr., and Chief Operations Officer, John Bolla. On February 20, 2020, we announced the signing of an amended and restated definitive agreement for the proposed merger of Progenics with Lantheus Holdings. The amended agreement reflects the renegotiation of certain of the terms of our original agreement for the proposed merger entered into on October 1, 2019. The definitive agreement provides that, following the closing, Dr. Ber and Mr. Mäusli, currently members of Progenics' Board, will be added as members of the Board of Directors of Lantheus Holdings. The transaction is expected to close early in the second quarter of 2020, subject to approval by Lantheus Holdings and Progenics stockholders, regulatory approvals, and certain other customary closing conditions.

AZEDRA®

- The AZEDRA commercial launch advanced in the U.S. AZEDRA 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 are available at www.AZEDRA.com
- The new technology add-on payment (NTAP) granted by the Centers for Medicare & Medicaid Services (CMS) for AZEDRA when administered in the hospital inpatient setting became effective on October 1, 2019 for Medicare beneficiaries in fiscal year 2020.
- The AZEDRA Global Managed Access program for appropriate commercial patients in need of the therapy outside the U.S. was initiated in October 2019, providing additional access to AZEDRA.
- In February 2019, we acquired the AZEDRA manufacturing facility located in Somerset, New Jersey. The Somerset site serves as the manufacturing facility for AZEDRA and will also provide manufacturing support for our development stage radiopharmaceuticals, including 1095.

1095

- In May 2019, we advanced our 1095 program and initiated a Phase 2 trial, dosing the first patient in June 2019. 1095 is a small molecule radiotherapeutic designed to selectively bind to the extracellular domain of 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 for CRPC, and progressed on abiraterone in the U.S. and Canada.

PyL™

- In August 2019, we completed enrollment of 208 patients at 14 sites in the United States and Canada in 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 five months ahead of schedule.
- In December 2019, we announced the results from start of a prospective, multicenter, open label pivotal Phase 3 CONDOR trial evaluating the diagnostic performance and clinical impact of PyL in men with biochemical recurrence of prostate cancer and uninformative baseline imaging based on conventional modalities. The CONDOR trial achieved its primary endpoint, with a correct localization rate (CLR) of 84.8% to 87.0% among the three blinded independent readers (the lower bound of the 95% confidence intervals ranging from 77.8% to 80.4%). Safety results showed PyL was well tolerated, consistent with the Phase 2/3 OSPREY trial results. There was one serious adverse event of hypersensitivity reported in one patient as related to the study drug. The most frequent adverse event reported was headache, which was reported in four patients (1.9% of the trial population).

Business Development

- In May 2019, we entered into an exclusive agreement under which ROTOP agreed to develop and commercialize 1404 in Europe. 1404 is Progenics' PSMA-targeted small molecule SPECT/CT imaging agent labeled with technetium-99m that is designed to visualize prostate cancer.
- In June 2019, we entered into a transfer agreement with FUJIFILM for the rights to the Company's aBSI product in Japan for use under the name BONENAVI®. In exchange, Progenics received \$4.0 million in an upfront payment and will receive service fees for aBSI and other AI products over three years in Japan. BONENAVI has been licensed to FUJIFILM for use in Japan since 2011.

Finance

- At the same time, we continued our focus on cost control and maintaining a sustainable cash burn rate.

We believe our program strongly links executive compensation with our performance. We have adopted a formal annual incentive plan based on metrics established by the Compensation Committee to provide a framework to determine annual bonus payments to NEOs and other key employees. As part of that process, we establish annual goals and objectives for the Company, and, as discussed below, determine bonuses based on how well we performed against these goals and objectives as determined by the Compensation Committee. For NEOs (other than our CEO), the annual bonus is also based on the Compensation Committee's assessment of the executive's individual performance during the year. We believe the annual bonus plan helps contribute to our growth and the creation of value for our shareholders.

A significant percentage of our NEOs' compensation is provided in the form of stock options that we believe further align their interests with those of our shareholders. The options we grant to our NEOs have an exercise price equal to the closing price of our Common Stock on the date of grant and will therefore have value only if our stock price increases. The options vest over a multi-year period to provide an additional retention incentive for our executives.

Elements of Compensation. We utilize a compensation structure that primarily includes base salary, an annual bonus opportunity and long-term incentives. These elements are designed to reward (i) core competence demonstrated in light of the executive's duties and responsibilities (base salary), (ii) decision-making that supports our annual product, development and financial goals (annual bonus), and (iii) a focus on building shareholder value over the long term in a sustainable manner by making decisions that will not sacrifice long-term prospects for a particular short-term achievement or goal (long-term incentives).

Base Salary. In setting levels of base salary for our executives, the Compensation Committee generally takes into account the individual's role and responsibilities, experience, expertise, individual performance and tenure. The Compensation Committee's view is that the NEO's base salaries should generally be set around the median level for the executive's position relative to the peer data provided by the Compensation Committee's consultant.

In February 2019, the Compensation Committee approved the following base salary levels for the NEOs for 2019: Mr. Baker \$654,901; Mr. Fabbio \$427,012; Mr. Osorio, \$394,200; and Dr. Wong \$434,372. These levels represented an increase of approximately 3% and 4% over the 2018 salary levels for Mr. Baker and Dr. Wong, respectively, and an increase of approximately 10% and 11% for Mr. Fabbio and Mr. Osorio, respectively, in light of their promotions during 2019. Dr. Das commenced employment with us in January 2019, and her starting base salary was set at \$450,000. The Compensation Committee determined in its judgment that each of these 2019 salary levels was appropriate, taking into account the peer company data provided by Frederic W. Cook & Co. ("FW Cook") and in light of the executive's tenure in his or her position and the other factors noted above.

As noted above, Mr. Mims was appointed as our Interim CEO in November 2019. Mr. Mims is compensated for his services as Interim CEO under a consulting agreement with the Company for a fee of \$30,000 per month.

Annual Bonus. Beginning in the fourth quarter of each year, the Compensation Committee works collaboratively with senior management to develop corporate goals and objectives for the annual bonus plan that are tied to strategic plans for the coming year. For 2019, the Compensation Committee established three corporate strategic and research and development goals, one commercial goal, and one financial goal to measure the Company's performance during the year. The table below reflects the weightings for each goal and the achievement scores awarded by the Compensation Committee at the end of the fiscal year in determining the NEOs' annual cash bonuses:

Performance Metric	Weight	Compensation Committee Assessment	Score Awarded
Maximize value of AZEDRA	35%	25% (partially met)	9%
Randomize first patient in 1095 Phase 2 trial (Q2)	25%	100%	25%
Complete enrollment in Phase 3 PyL CONDOR study (Q4)	20%	120% (exceeded)	24%
Business development adds to the Company's pipeline	15%	80% (partially met)	12%
Finance manages expenses and financing	5%	75% (partially met)	4%
Total	100%		75%*

* The Compensation Committee exercised discretion to increase the final corporate performance percentage slightly from 74% to 75% based on its subjective assessment of the Company's overall performance in 2019.

The Compensation Committee's assessment for each goal was as follows:

- *Maximize value of AZEDRA* (25% of target): The Corporate goal to maximize the value of AZEDRA included successfully manufacturing and delivering product to patients, achieving budgeted net sales, as well as a successful FDA meeting and enrollment of the first patient in an LCM study. The Compensation Committee determined that the Company performed at 25% of target given that the LCM study was not initiated, budgeted net sales were not achieved but significant progress was made in successfully manufacturing product.
- *Randomize first patient in 1095 Phase 2 trial (Q2)* (100% of target): The Compensation Committee determined that the Company performed at 100% of target for this goal given that the first patient was randomized in the 1095 Phase 2 trial in the second quarter.
- *Complete enrollment in Phase 3 PyL CONDOR study (Q4)* (120% of target): The Compensation Committee determined that the Company performed at 120% of target for this goal given enrollment for the phase 3 PyL CONDOR study was completed five months ahead of plan.
- *Business development adds to the Company's pipeline* (80% of target): Although the Company did not complete a product or company acquisition during 2019, the Compensation Committee determined that the Company partially met this goal due to the completion of an out-license with ROTOP, the transfer agreement with Fuji for aBSI and the execution of the merger agreement with Lantheus Holdings.
- *Finance manages expenses and financing* (75% of target): The Compensation Committee determined that the Company performed at 75% of target for this goal given that, although the Company did not deliver on its expense and financing target, the Compensation Committee noted that there were exceptional expenses during the year related to the activist defense and the execution of the Lantheus Holdings merger agreement.

Target bonus amounts were established for each executive based on a percentage of the executive's base salary and are generally set at levels the Compensation Committee believes to be competitive. For 2019, Mr. Baker's bonus target was 50% of his base salary, and his bonus opportunity was based entirely on achievement of the corporate goals listed above. The target bonus amounts for the other NEOs were set by the Compensation Committee in its judgment, taking into account Mr. Baker's recommendations, and are presented in a table below. For each NEO other than Mr. Baker, the target bonus amount was 35% of the executive's base salary (or, for Dr. Das, 40% of her base salary) and the bonus opportunity was allocated 75% and 25% to the achievement of corporate goals and the NEO's individual performance, respectively. In each case, the Compensation Committee caps the achievement percentage for each goal at 150% of target, which effectively caps annual incentive bonus payments at 150% of the target award amount regardless of how many goals are met or exceeded. Bonuses are generally paid in the first quarter of the following year.

As Mr. Baker resigned as our CEO in November 2019, he was not eligible for a bonus under our program. Mr. Mims also was not eligible to participate in the program for 2019. The actual bonus amounts for the other NEOs were determined by the Compensation Committee based on its assessment of achievement of the corporate goals identified above and the individual NEO's performance during the year. In each case, the NEO's bonus is capped at 150% of the NEO's target bonus amount. As noted above, the Compensation Committee approved an achievement percentage of 75% for the corporate goals. Consistent with its decision over the last few years, the Compensation Committee did not establish individual goals for the NEOs. Instead, the Compensation Committee reviewed the individual performance of each NEO and the NEO's role in achieving the corporate goals. The Compensation Committee determined in reviewing the performance of the management team it would be appropriate to award each NEO an individual performance factor between 95% and 105% as specified below.

In assessing the 2019 individual performance of each of our NEOs, the Compensation Committee noted in particular:

- Mr. Fabbio spearheaded the acquisition of the Somerset manufacturing site, managed the Company's operations against budgeted targets and played an integral role in the negotiation, execution and integration planning for the Lantheus Holdings merger.
- Mr. Osorio led the transition of AZEDRA manufacturing assets to the Company, developed the Company's Somerset organization and successfully transferred and optimized the AZEDRA manufacturing process. His group also provided chemistry manufacturing and controls support for the upcoming PyL NDA filing.
- Dr. Das helped build and grow the Medical Affairs department with key opinion leader engagement and a presence at important medical conferences, including presentation of scientific information. These activities provide medical affairs support for the initiation of market planning and preparation of the PyL launch and for the ongoing AZEDRA launch.
- Dr. Wong led the successful completion of a PyL phase 3 trial five months ahead of schedule and delivered positive results pivotal for an NDA filing. In addition, Dr. Wong spearheaded the advancement of a PSMA therapeutic to phase 2 testing.

For the individual NEOs, the Compensation Committee awarded annual incentive bonus payments as follows:

NEO	2019 Salary	2019 Bonus Target as % of Salary	2019 Bonus Target	Corporate Weighting x Corporate Score	Individual Weighting x Individual Score	% of Bonus Target Awarded	2019 Bonus Awarded
Patrick Fabbio	\$ 427,102	35%	\$ 149,454	75% x 75%	25% x 105%	82.5%	\$ 123,300
Benedict Osorio	\$ 394,200	35%	\$ 137,970	75% x 75%	25% x 95%	80.0%	\$ 110,376
Asha Das	\$ 450,000	40%	\$ 180,000	75% x 75%	25% x 105%	82.5%	\$ 148,500
Vivien Wong	\$ 434,372	35%	\$ 152,030	75% x 75%	25% x 105%	82.5%	\$ 125,425

Discretionary Bonuses. The Compensation Committee may also award discretionary bonuses from time to time as it deems appropriate. The Compensation Committee approved a signing bonus of \$25,000 for Dr. Das in connection with her commencing employment with the Company in January 2019. Dr. Das is obligated to repay her bonus to the Company in case of her voluntary termination of employment within 180 days of her start date.

In October 2019, the Compensation Committee approved retention payment opportunities for approximately one-half of the employees of the Company, including each of the Company's executive officers then employed with the Company (other than Mr. Baker), to provide a retention incentive for the award recipient to remain employed with the Company and sustain the Company's operations through the closing of the pending acquisition of the Company by Lantheus Holdings, Inc. (the "Closing") and for a period of up to six months after the Closing. Each retention payment opportunity provides that if the award recipient remains employed with the Company through the Closing, and the Closing occurs on or before July 1, 2020, the award recipient will be entitled to a payment of 50 percent of his or her total retention payment opportunity. If the Closing occurs on or before July 1, 2020 and the award recipient remains employed with the Company for six months after the Closing (or the award recipient's employment is terminated during that six-month period by the Company without cause, by the award recipient for good reason, or due to the award recipient's death or disability), the award recipient will be entitled to a payment of the remaining 50 percent of his or her total retention payment opportunity. The total retention payment opportunity for each of the NEOs who received this opportunity (i.e., Mr. Fabbio, Mr. Osorio, Dr. Das and Dr. Wong) is \$180,000. The Compensation Committee determined that these awards were appropriate to help maintain the Company's operations and performance through the Closing and the integration period following the Closing.

Long-Term Incentives. For 2019, as we have done in prior years, we granted long-term incentives to the NEOs in the form of stock options under our 2018 Performance Incentive Plan (the “2018 Plan”). As a development-stage life science company, we believe stock options provide a strong link to performance as our stock price is closely tied to our performance against research and development goals and is less easily influenced by outside market conditions than for other sectors. The exercise prices of these options were set at the closing price of our Common Stock on the grant date, so the options will only have value if our stock price increases after the grant date, further aligning the interests of our executives with those of our shareholders. The options vest generally in equal annual installments over three years from the date of grant subject to the executive’s continued employment through the vesting date, although the Compensation Committee may establish different vesting requirements as it deems appropriate for a particular award (for example, in connection with a new-hire or promotion grant). The Compensation Committee believes that stock options provide appropriate incentives for executives both to increase value on a long-term basis for our shareholders and to continue in service with us.

When determining the grant levels of long-term incentive awards to our NEOs, the Compensation Committee compares (i) the value of the grant with the value of comparable grants made to executive officers in our peer group as discussed above; (ii) the number of shares granted by position as a percentage of our total common shares outstanding, compared with the applicable percentages of comparable grants made to executives in our peer group; and (iii) the executive’s overall equity incentive opportunity, compared with the applicable overall equity incentive for executives in our peer group. The Compensation Committee believes these comparisons provide a meaningful context for assessing the competitive level of our equity grants and help ensure that we are not at a competitive disadvantage in terms of hiring or retaining key executive talent. As noted above, the Compensation Committee determines the levels of equity grants and other compensation in its judgment, uses the peer group information as background reference only and does not benchmark equity awards at any particular level relative to the peer group.

In February 2019, the Compensation Committee approved grants of stock options to each of the NEOs then employed with us. The number of shares subject to the grant made to each NEO in 2019 was lower than the grant level awarded to the NEO in 2018, and the value of each NEO’s 2019 option (based on the grant date fair value of the option as determined for accounting purposes) was significantly lower than the value of the NEO’s 2018 option as reflected in the table below.

NEO	2019 Stock Options Granted #	2018 Stock Options Granted #	2019 Stock Options Grant Date Fair Value (\$)	2018 Stock Options Grant Date Fair Value (\$)	Year over Year Changes in Grant Date Fair Value (%)
Mr. Baker	192,500	201,250	\$ 598,514	\$ 928,058	(35.5%)
Mr. Fabbio	90,750	94,875	\$ 282,157	\$ 437,513	(35.5%)
Mr. Osorio	90,750	100,000	\$ 282,157	\$ 461,147	(38.8%)
Dr. Das	125,000	N/A	\$ 393,454	N/A	N/A
Dr. Wong	90,750	94,875	\$ 282,157	\$ 437,513	(35.5%)

As Dr. Das joined the Company in January 2019, the Compensation Committee approved a new grant to her of 125,000 options that will vest over a five-year period. More information on the options granted to our NEOs during 2019 and awards outstanding from prior grants are presented in the *Grants of Plan-Based Awards in 2019* and *Outstanding Equity Awards at 2019 Fiscal Year-End* tables, below.

We generally grant annual equity awards near the beginning of the year (typically in March) to coincide with other compensation decisions. We may also grant awards to newly-hired employees or at other times during the year as deemed appropriate by the Compensation Committee.

Retirement, Welfare Benefits. We make available to our NEOs retirement and welfare benefits, consisting of participation in, and partial matching contributions by us to, our 401(k) retirement plan and access to medical, dental, and other welfare plans, all of which are available to all full-time employees. NEOs also receive reimbursement of premiums for enhanced life and disability insurance, totaling less than \$10,000 per NEO, and we generally do not provide material perquisites to our NEOs. This approach is consistent with our view that company resources are generally best utilized in research, development and commercialization efforts. The total of these benefits in 2019 for each NEO is presented in the *Summary Compensation Table*, below.

Severance Benefits; No Tax Gross-Ups. We do not have employment or other severance agreements with any of our NEOs, although we do provide accelerated vesting of equity awards if an NEO is terminated by the Company without cause in connection with a change in control. We do not provide any of our executives with reimbursements or “gross-up” payments for any taxes incurred pursuant to Section 280G of the IRC or otherwise.

Compensation and Risk. We do not believe, given the nature of our activities and the manner in which our employees are compensated, that risks arising from our compensation policies and practices relating to all of our employees are reasonably likely to have a material adverse effect on us. As described above, the Compensation Committee establishes multiple performance goals for the annual incentive plan and believes that this structure mitigates the risk associated with overemphasis on a particular performance metric. In its assessment of the achievement of these annual performance goals, the Compensation Committee caps the annual incentive bonus payments at 150% of the target award amount regardless of how many goals are met or exceeded. A significant portion of our NEOs’ compensation is in the form of equity-based awards that are intended to further align the interests of our executives with those of our shareholders and provide additional incentives to focus on the long-term success of our company.

Tax Considerations. Federal income tax law generally prohibits a publicly-held company from deducting compensation paid to a current or former named executive officer that exceeds \$1 million during the tax year. Certain awards granted before November 2, 2017 that were based upon attaining pre-established performance measures that were set by the Compensation Committee under a plan approved by the Company’s shareholders, as well as amounts payable to former executives pursuant to a written binding contract that was in effect on November 2, 2017, may qualify for an exception to the \$1 million deductibility limit. As one of the factors in its consideration of compensation matters, the Compensation Committee notes this deductibility limitation. However, the Compensation Committee has the flexibility to take any compensation-related actions that it determines are in the best interests of the Company and our shareholders, including awarding compensation that may not be deductible for tax purposes. There can be no assurance that any compensation will in fact be deductible.

Executive Compensation Philosophy and Process

Executive Compensation Objectives. We seek to achieve the following broad goals in our executive compensation programs and decisions regarding individual compensation:

- Attract and retain executives critical to our overall success.
- Reward executives for contributions to achieving strategic goals that enhance shareholder value.
- Foster and maintain a company culture of ownership, creativity and innovation.
- Motivate our NEOs to achieve critical long- and short-term development, product and financial milestones set by the Board in consultation with management.

General Compensation Process. The Compensation Committee is responsible for determining the elements and levels of compensation for our NEOs. In doing so, it reviews our corporate performance against financial and corporate achievement measures, assesses individual performance and evaluates recommendations of the CEO regarding compensation for other NEOs.

The process the Compensation Committee followed in assessing the NEOs’ and the Company’s performance for 2019 began, as has been the Compensation Committee’s practice in the past, with meetings in early 2019 that were principally focused on approving bonuses relating to 2018 performance and establishing 2019 salary, target bonus and equity grant levels. In those meetings, Mr. Baker was invited to make an oral presentation and submit to the Compensation Committee written materials regarding the performance of the NEOs and other officers, his views regarding the performance of the Company, and his assessment of his own performance. Mr. Baker neither participated in nor was present for decisions regarding his own compensation.

To assist in its deliberations regarding executive compensation for 2019, the Compensation Committee directly engaged FW Cook as its compensation consultant. FW Cook does not undertake any work for us other than its services for the Compensation Committee. The Compensation Committee has determined that FW Cook is independent and that its services do not raise any conflict of interest with us or any of our executive officers or directors. In carrying out its work for the Compensation Committee, FW Cook interacts from time to time directly with our management, as it determines appropriate, regarding its work product prior to presentation to the Compensation Committee in order to confirm alignment with our business strategy and obtain data or information necessary for its work.

FW Cook reviewed and discussed with the Compensation Committee competitive market compensation data for consideration when determining different levels and mix of compensation for 2019. The Compensation Committee reviewed publicly available compensation information of executive officers of a peer group of companies within the biotechnology industry. This peer group was selected by the Compensation Committee with FW Cook's assistance in 2018 and consisted of companies that were similar to the Company in size, business model and state of development at that time. In selecting the peer group, we typically focus on companies with one-year average market capitalization of 0.2 to 5 times our one-year average market capitalization, total employees of 0.5 to 2 times our total employees and three-year average revenues of 0.4 to 2.5 times our three-year average revenue. We use averages for revenues and market capitalization because of the high volatility of these metrics at early-stage life sciences companies. We may also make exceptions to these parameters in certain cases as the Compensation Committee determines appropriate.

In making its 2019 executive compensation decisions, the Compensation Committee determined that it would be reasonable to use the same peer group of companies it had selected in 2018 (except that Sucampo Pharmaceuticals, Inc. was removed from the group as it was acquired during 2018). Accordingly, for 2019, the peer group companies consisted of the following companies:

Agenus Inc.	Immunomedics Inc.
Array Biopharma Inc.	MacroGenics, Inc.
BioCryst Pharmaceuticals, Inc.	OncoMed Pharmaceuticals, Inc.
BioDelivery Sciences International, Inc.	Rigel Pharmaceuticals, Inc.
CTI BioPharma Corp.	Vanda Pharmaceuticals, Inc.
Curis, Inc.	Xencor, Inc.
GTx Inc.	XOMA Corporation

The peer company compensation data provided by FW Cook is used by the Compensation Committee as a general reference point in its compensation review. The Compensation Committee does not set compensation levels at any specific level or percentile against this compensation data (*i.e.*, the Compensation Committee does not “benchmark” our executive compensation levels). The peer group data is only one point of information taken into account by the Compensation Committee in making compensation decisions as noted below.

In addition to Mr. Baker's recommendations regarding the other NEOs and its review of market data, the Compensation Committee considered various other factors in setting the NEOs' 2019 target compensation opportunities such as the individual's corporate roles and responsibilities, particular experience and expertise, performance and specific duties, the scope of his or her position and the department(s) or group(s) for which he or she had responsibility, our overall corporate financial performance and the progress of our research and development programs and strategic initiatives during the year. The Compensation Committee does not assign any particular weighting to any factor and has discretion to consider whatever factors it may deem relevant to a particular decision. Except as otherwise noted in this Compensation Discussion and Analysis, decisions by the Compensation Committee are subjective and the result of the Compensation Committee's business judgment, which is informed by the experiences of the members of the Compensation Committee as well as analysis and input from, and comparable peer data provided by, the Compensation Committee's independent compensation consultants.

Shareholder Advisory Vote on Executive Compensation

We provide our shareholders with the opportunity to cast an annual advisory vote to approve our executive compensation program (referred to as a “say-on-pay proposal”). At our annual meeting of shareholders held in July 2019, approximately 55% of the votes actually cast on the say-on-pay proposal were voted in favor of the proposal. The Compensation Committee believes these results affirm shareholders' support of our approach to our executive compensation program. In general, the Compensation Committee did not change its approach in 2019 and believes the program in place reflects the goals of our program and best practices in the market. The Compensation Committee will continue to consider the outcome of our say-on-pay proposals when making future compensation decisions for the NEOs.

Summary Compensation Table - 2017 - 2019

The table and footnotes below describe the total compensation paid to our NEOs for the years 2019, 2018, and 2017 as identified in the table below. As reflected in the table and discussed above in the *Compensation Discussion and Analysis*, we compensate these executive officers primarily with a combination of cash and stock options, the latter of which is presented in this table in dollar values (see note 1 and the equity compensation tables that follow). We did not issue any other types of equity awards (such as restricted stock or stock unit awards) in 2019.

Name and Principal Position	Year	Salary	Bonus(1)	Option Awards(2)	Non-Equity Incentive Plan Compensation(1)	All Other Compensation(3)	Total
David W. Mims(4) <i>Interim CEO</i>	2019	\$ 45,000	\$ -	\$ 180,572	\$ -	\$ 5,810	\$ 231,382
Mark R. Baker(5) <i>Former CEO</i>	2019	\$ 563,383	\$ -	\$ 598,514	\$ -	\$ 21,132	\$ 1,183,029
	2018	\$ 632,755	\$ -	\$ 928,058	\$ 287,904	\$ 18,693	\$ 1,867,410
	2017	\$ 614,325	\$ -	\$ 1,373,141	\$ 307,163	\$ 18,507	\$ 2,313,136
Patrick Fabbio(6) <i>Executive Vice President and CFO</i>	2019	\$ 422,845	\$ -	\$ 282,157	\$ 123,300	\$ 15,537	\$ 843,839
	2018	\$ 386,550	\$ -	\$ 437,513	\$ 134,616	\$ 15,472	\$ 974,151
	2017	\$ 375,291	\$ -	\$ 647,338	\$ 131,352	\$ 15,185	\$ 1,169,166
Benedict Osorio(7) <i>COO</i>	2019	\$ 390,033	\$ -	\$ 282,157	\$ 110,376	\$ 18,217	\$ 800,783
	2018	\$ 305,391	\$ 80,000	\$ 461,147	\$ 106,321	\$ 14,555	\$ 967,414
Asha Das(8) <i>Chief Medical Officer</i>	2019	\$ 448,558	\$ 25,000	\$ 393,454	\$ 148,500	\$ 32,913	\$ 1,048,425
Vivien Wong <i>Executive Vice President, Development</i>	2019	\$ 434,372	\$ -	\$ 282,157	\$ 125,425	\$ 17,157	\$ 859,111
	2018	\$ 419,683	\$ -	\$ 437,513	\$ 142,482	\$ 18,045	\$ 1,017,723
	2017	\$ 407,459	\$ -	\$ 647,338	\$ 151,524	\$ 17,971	\$ 1,224,292

- (1) The amounts reported in the “Non-Equity Incentive Plan Compensation” column represent cash bonuses awarded under our annual incentive plan, while the amounts in the “Bonus” column represent discretionary bonuses awarded to certain NEOs during the applicable fiscal year. Each of the NEOs’ 2019 bonuses is described in the *Compensation Discussion and Analysis* above.
- (2) The amounts reported in this column for each NEO reflect the aggregate grant date fair value of stock options granted to the NEO during the applicable fiscal year. The fair values were determined based on the assumptions for calculating expense amounts as set forth in the notes to our consolidated financial statements included in our Annual Report on Form 10-K for the relevant years (For 2019 grants, see Note 11 - Stock-Based Compensation, in our consolidated financial statements included herein). Additional information on the 2019 awards is included in the *Grants of Plan-Based Awards for 2019* and *Outstanding Equity Awards at 2019 Fiscal Year-End* tables, below.
- (3) The amounts reported in this column for 2019 for each NEO (other than Mr. Mims) include our matching contribution under our 401(k) Plan in the amount of \$12,500 for Mr. Baker, \$12,500 for Mr. Fabbio, \$12,500 for Mr. Osorio, \$12,500 for Dr. Das, and \$11,450 for Dr. Wong. This column also includes payments of premiums for enhanced life and disability insurance for Mr. Baker (\$8,632), Mr. Fabbio (\$3,037), Mr. Osorio (\$5,717), Dr. Das (\$3,998), and Dr. Wong (\$5,707) and reimbursement of moving expenses for Dr. Das of \$16,415.
- (4) Mr. Mims was appointed as our Interim CEO, effective November 15, 2019. The amount reported in the “Salary” column for Mr. Mims reflects his fees under his consulting agreement with the Company described below. Mr. Mims also serves on our board of directors and received a stock option grant and cash fees for his service on the board during 2019. The amounts in the “Option Awards” column and the “All Other Compensation” column reflect the grant date fair value of this stock option and the amount of his director fees for 2019, respectively.
- (5) Mr. Baker resigned as our CEO, effective November 11, 2019.
- (6) Mr. Fabbio has notified the Company that he intends to resign as Executive Vice President and CFO, effective March 27, 2020. He has agreed to continue providing services to the Company as a consultant following his resignation until the earlier of the closing of the Company’s proposed acquisition by Lantheus Holdings or May 15, 2020.
- (7) Mr. Osorio joined the Company in February 2018.
- (8) Dr. Das joined the Company in January 2019.

Employment Letters

In connection with his appointment as Senior Vice President and CFO in November 2015, we entered into an offer letter with Mr. Fabbio. The letter provides for a starting annual base salary of \$350,000 and eligibility to participate in our annual cash incentive plan, with a target bonus opportunity equal to 35% of base salary. Mr. Fabbio was promoted to Executive Vice President and CFO on March 1, 2019. The Compensation Committee increased Mr. Fabbio’s base salary most recently to \$427,012 per year for 2019. The letter includes certain non-competition, non-solicitation, and other restrictive covenants in our favor.

In connection with his appointment as Senior Vice President, Quality in February 2018, we entered into an offer letter with Mr. Osorio. The letter provides for a starting annual base salary of \$355,000, sign on bonus of \$80,000 and eligibility to participate in our annual cash incentive plan, with a target bonus opportunity equal to 35% of base salary. Mr. Osorio was promoted to COO on March 1, 2019. The Compensation Committee approved Mr. Osorio's promotion to COO and increased his base salary most recently to \$394,200 per year for 2019. The letter includes certain non-competition, non-solicitation, and other restrictive covenants in our favor.

In connection with her appointment as Chief Medical Officer in January 2019, we entered into an offer letter with Dr. Das. The letter provides for a starting annual base salary of \$450,000, sign-on bonus of \$25,000 and eligibility to participate in our annual cash incentive plan, with a target bonus opportunity equal to 40% of base salary. Dr. Das is obligated to repay her sign-on bonus to the Company in case of her voluntary termination of employment within 180 days of her start date. The letter also provides for the Company to reimburse up to \$25,000 for her moving expenses in connection with joining the Company. The letter includes certain non-competition, non-solicitation, and other restrictive covenants in our favor.

Grants of Plan-Based Awards in 2019

The following table sets forth information regarding grants of incentive compensation awards we made to our NEOs during 2019.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Share)	Grant Date Fair Value of Stock and Option Awards(3)
		Threshold (\$)	Target (\$)	Maximum (\$)			
Mr. Mims	12/13/2019	-	-	-	40,000	\$ 5.01	\$ 128,081
	12/13/2019	-	-	-	16,393	\$ 5.01	\$ 52,491
Mr. Baker	3/1/2019				192,500	\$ 4.52	\$ 598,514
	N/A	-	\$ 327,451	\$ 491,176			
Mr. Fabbio	3/1/2019				90,750	\$ 4.52	\$ 282,157
	N/A	-	\$ 149,454	\$ 224,181			
Mr. Osorio	3/1/2019				90,750	\$ 4.52	\$ 282,157
	N/A	-	\$ 137,970	\$ 206,955			
Dr. Das	3/1/2019				125,000	\$ 4.56	\$ 393,454
	N/A	-	\$ 180,000	\$ 270,000			
Dr. Wong	3/1/2019				90,750	\$ 4.52	\$ 282,157
	N/A		\$ 152,050	\$ 228,045			

- (1) These columns reflect opportunities to receive a bonus under our annual incentive plan for 2019. The terms of the plan are described in the *Annual Bonus* discussion under *Compensation Discussion and Analysis*, above.
- (2) These option grants (other than the grants to Mr. Mims and Dr. Das) vest in equal annual installments over the three-year period beginning March 1, 2019. Mr. Mims' grant of 16,393 options was fully vested at grant. His grant of 40,000 options and Dr. Das' grant each vest over five years. In each case, vesting is contingent on the executive's continued employment through the vesting date.
- (3) These amounts reflect the aggregate grant date fair value of the award determined based on the assumptions described in note 1 to the *Summary Compensation Table* above.

Each of the stock option awards reported in the table above was granted under our 2018 Plan. The 2018 Plan is administered by the Compensation Committee, which has authority to interpret the plan provisions and make all required determinations. Plan awards are generally only transferable to a beneficiary of an awardee upon his or her death or, in certain cases, to family members for tax or estate planning purposes. If there is a change in control of the Company, the Compensation Committee may provide for the treatment of outstanding awards upon the transaction, including acceleration of vesting, elimination, or modification of performance or other conditions, extension of time to exercise or realize gain, acceleration of payment or cash settlement. The Compensation Committee has determined that all outstanding stock incentive awards held by a Company employee will vest in full if the employee is terminated by the Company without Cause during the one-year period following a Change in Control (as such terms are defined in the 2018 Plan and our form of stock incentive award agreement).

Outstanding Equity Awards at 2019 Fiscal Year-End

The table below sets forth information regarding unexercised stock options held by our NEOs as of December 31, 2019. None of our NEOs held any unvested restricted stock or stock unit awards at December 31, 2019.

Name	Option Awards				
	No. of Securities Underlying Unexercised Options (#) Exercisable	No. of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: No. of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price	Option Expiration Date
Mr. Mims	16,393	-	-	\$ 5.01	12/13/2029
	-	40,000 (1)	-	\$ 5.01	12/13/2029
Mr. Baker(2)	67,083	-	-	\$ 6.62	3/1/2028
	116,666	-	-	\$ 11.32	3/1/2027
	35,817	-	-	\$ 4.52	3/1/2026
	132,000	-	-	\$ 6.65	3/2/2025
	132,000	-	-	\$ 4.70	3/3/2024
	120,000	-	-	\$ 5.03	4/3/2023
	66,666	-	-	\$ 9.81	3/1/2022
	62,500	-	-	\$ 7.40	7/1/2021
	46,875	-	-	\$ 7.40	7/1/2021
	200,000	-	-	\$ 7.66	6/8/2021
	125,000	-	-	\$ 5.35	7/1/2020
	150,000	-	-	\$ 5.35	7/1/2020
Mr. Fabbio	-	90,750 (3)	-	\$ 4.52	3/1/2029
	31,625	63,250 (4)	-	\$ 6.62	3/1/2028
	55,000	27,500 (5)	-	\$ 11.32	3/1/2027
	82,500	-	-	\$ 4.52	3/1/2026
	100,000	25,000 (6)	-	\$ 6.77	12/1/2025
Mr. Osorio	-	90,750 (3)	-	\$ 4.52	3/1/2029
	20,000	80,000 (7)	-	\$ 6.62	3/1/2028
Dr. Das	-	125,000 (8)	-	\$ 4.56	2/1/2029
Dr. Wong	-	90,750 (3)	-	\$ 4.52	3/1/2029
	31,625	63,250 (4)	-	\$ 6.62	3/1/2028
	55,000	27,500 (5)	-	\$ 11.32	3/1/2027
	82,500	-	-	\$ 4.52	3/1/2026
	66,000	-	-	\$ 6.65	3/2/2025
	52,800	-	-	\$ 4.70	3/3/2024
	75,000	-	-	\$ 4.70	3/3/2024
	48,000	-	-	\$ 5.03	4/4/2023
	40,000	-	-	\$ 9.81	3/1/2022
	60,000	-	-	\$ 7.40	7/1/2021
	25,000	-	-	\$ 4.83	11/1/2020
	6,000	-	-	\$ 5.35	7/1/2020

(1) These options vest in five annual installments measured from December 13, 2019.

(2) To the extent not previously exercised, each of Mr. Baker's options terminated on February 9, 2020.

(3) These options vest in three annual installments measured from March 1, 2019.

(4) These options vest in three annual installments measured from March 1, 2018.

(5) These options vest in three annual installments measured from March 1, 2017.

(6) These options vest in five annual installments measured from December 1, 2015.

(7) These options vest in five annual installments measured from March 1, 2018.

(8) These options vest in five annual installments measured from February 1, 2019.

Option Exercises and Stock Vested in 2019

The following table sets forth information regarding the exercise of stock options by our NEOs during 2019. Our NEOs did not hold any outstanding restricted stock or stock unit awards during 2019.

	Option Awards	
	No. of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)(1)
Mr. Mims	-	-
Mr. Baker	139,183	189,038
Mr. Fabbio	-	-
Mr. Osorio	-	-
Dr. Das	-	-
Dr. Wong	-	-

- (1) The dollar amounts shown in this column for option awards are determined by multiplying (i) the number of shares of our common stock to which the exercise of the option related, by (ii) the difference between the closing price per share of our common stock on the date of exercise and the per-share exercise price of the options.

Potential Payments upon Termination or Change in Control

We have no employment or other agreements with any of our NEOs that provide for severance benefits. As a result, the only benefits which the NEOs who are currently employed by us would be entitled to receive upon termination of employment or a change in control of the Company would be accelerated vesting of their equity awards if the executive is terminated by the Company without cause during the one-year period following a change in control (or, in the case of the option granted to Mr. Mims in December 2019 in connection with his service on our board of directors, accelerated vesting of his option upon a change in control only), as provided in the applicable award agreements. The table below sets forth the value of each executive's then-outstanding and unvested stock options that would have accelerated if a change in control of the Company and a termination of the executive's employment without cause had occurred on December 31, 2019:

Name	Value of Unvested Options (\$)(1)
Mr. Mims	3,200
Mr. Baker	-
Mr. Fabbio	51,728
Mr. Osorio	51,728
Dr. Das	66,250
Dr. Wong	51,728

- (1) The value of these options was determined by multiplying the number of shares subject to the unvested options by the amount, if any, by which the closing price of our common stock on the last trading day of fiscal 2019 (\$5.09) exceeded the option exercise price). Unvested options with a per-share exercise price greater than \$5.09 were treated as having no value for purposes of this calculation.

As noted above, we do not provide reimbursement or gross-up payments to NEOs for parachute payment taxes incurred in connection with a change in control.

Director Compensation - 2019

The following table sets forth information regarding the aggregate compensation we paid for 2019 to the members of our Board who are not employed by us or any of our subsidiaries ("non-employee directors"). Mr. Baker, our former CEO, did not receive any additional compensation for services provided as a Board member during 2019. The compensation provided to Mr. Mims, who serves as our Interim CEO, for his services to the Company during 2019 is set forth in the *Summary Compensation Table* above.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) ⁽¹⁾	All Other Compensation (\$)	Total (\$)
Gerard Ber ⁽²⁾	10,330	180,572	-	190,902
Bradley L. Campbell	70,404	96,699	-	167,103
Peter J. Crowley ⁽³⁾	82,299	212,737	-	295,036
Eric J. Ende ⁽²⁾	11,234	180,572	-	191,806
Karen J. Ferrante	73,331	96,699	-	170,030
Michael D. Kishbauch ⁽³⁾	61,188	96,699	-	157,887
Ann MacDougall ⁽²⁾	12,184	243,562	-	255,746
Heinz Mäusli ⁽²⁾	10,975	180,572	-	191,547
David A. Scheinberg ⁽⁴⁾	70,247	96,699	-	166,946
Nicole S. Williams ⁽⁴⁾	73,696	96,699	-	170,395

- (1) At December 31, 2019, the aggregate number of stock options outstanding for each of our non-employee directors was as follows: Dr. Ber, 56,393; Mr. Campbell, 98,000; Mr. Crowley, 423,749; Dr. Ende, 56,393; Dr. Ferrante, 170,000; Mr. Kishbauch, 166,591; Ms. MacDougall, 76,065; Mr. Mäusli, 56,393; Dr. Scheinberg, 180,000; and Ms. Williams, 180,000. On the date of our 2019 annual meeting of stockholders, Mr. Campbell, Mr. Crowley, Dr. Ferrante, Mr. Kishbauch, Dr. Scheinberg and Ms. Williams were each granted an option with respect to 25,000 shares of our Common Stock (except that the Chair option grant for Mr. Crowley covered 55,000 shares), with each such option vesting in 12 monthly installments after the grant date. In December 2019, Dr. Ber, Dr. Ende, Ms. MacDougall and Mr. Mäusli were each granted (a) an option with respect to 40,000 shares of our Common Stock that vests in five annual installments after the grant date and (b) an option with respect to 16,393 shares of our Common Stock (except that the Chair option grant for Ms. MacDougall covered 36,065 shares) that was fully vested upon grant (such grants representing a pro-rated portion of the grants made to the other non-employee directors at the 2019 annual meeting). The grant date fair value of the options granted to each non-employee director are set forth above in the “Option Awards” column. In each case, the grant date fair values of the options granted to our non-employee directors are determined based on the assumptions described in Note 2 to the *Summary Compensation Table* above for the Named Executive Officers.
- (2) Dr. Ber, Dr. Ende, Ms. MacDougall and Mr. Mäusli each joined the Board, effective November 8, 2019.
- (3) Mr. Crowley and Mr. Kishbauch each resigned from the Board, effective October 17, 2019.
- (4) Dr. Scheinberg and Ms. Williams each were removed from the Board without cause, effective November 8, 2019.

For Board and committee service under our director compensation policy, our non-employee directors are entitled to receive:

- a \$45,000 annual retainer for Board service (\$75,000 for service as Chair; currently Ms. MacDougall), an annual retainer fee for committee service as (i) Audit Committee member (\$10,000) or Chair (\$35,000; currently Mr. Mäusli); (ii) Compensation Committee member (\$7,000) or Chair (\$22,000; currently Dr. Ende); (iii) Nominating and Corporate Governance Committee member (\$5,000) or Chair (\$13,000; currently Ms. MacDougall); and (iv) Science Committee member (\$10,000) or Chair (\$35,000; currently Dr. Ber); and
- a fully-vested option for 25,000 common shares (55,000 in the case of the Chair) and, for newly-appointed directors joining the Board, a one-time option for 40,000 common shares vesting over five years.

Option awards for Board service are granted under the 2018 Plan (or any successor plan thereto). These options each have a ten-year term and have an exercise price equal to the closing price of our stock on the grant date. These options will generally become fully vested upon a termination of the director’s service on the Board due to death or disability or certain transactions that constitute a change in control of the Company.

Pay Ratio Disclosure

In accordance with Item 402(u) of Regulation S-K, promulgated by the SEC pursuant to the Dodd-Frank Wall Street Reform Act and Consumer Protection Act of 2010, we are required to disclose the ratio of the annual total compensation of our CEO relative to the median annual total compensation of all of our employees (excluding our CEO). For our CEO’s total compensation, we used the aggregate compensation for Mr. Baker and Mr. Mims, who each served as our CEO for a portion of 2019.

Based on SEC rules for this disclosure and the methodology described below, for 2019, the ratio of the annual total compensation of our CEO to the median of the annual total compensation of all employees was 8 to 1.

Employee Population. We selected December 31, 2019, which is a date within the last three months of fiscal 2019, as the date we would use to identify our median employee. As of December 31, 2019, our global employee population consisted of 105 employees at Progenics and its consolidated subsidiaries. This includes 92 U.S. employees.

Methodology. In determining the median employee, a list of all employees (exclusive of our CEO) was prepared based on all active employees included in our payroll records as of December 31, 2019. We used base compensation as the measure to identify the median employee from this list. Salaries and wages were annualized for those employees who were employed by us on December 31, 2019 but were not employed for the full year of 2019.

Pay-Ratio Calculation. The total annual compensation of the median employee was then calculated in the same manner as the total aggregate compensation disclosed for Mr. Baker and Mr. Mims in the *Summary Compensation Table* above.

Annual total compensation of CEO	\$	1,414,411
Annual total compensation of the median employee		185,375
Ratio of CEO to median employee compensation		8 : 1

This pay ratio is an estimate calculated in a manner consistent with SEC rules based on the methodology described above. The SEC rules for identifying the median compensated employee and calculating the pay ratio based on that employee's annual total compensation allow companies to adopt a variety of methodologies, to apply certain exclusions, and to make reasonable estimates and assumptions. As such, the pay ratio reported by other companies may not be comparable to the pay ratio reported above, as other companies may have different employment and compensation practices and may utilize different methodologies, exclusions, estimates, and assumptions in calculating their own pay ratios.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information as of March 2, 2020, except as noted, regarding the beneficial ownership of the common stock by (i) each person or group known to us to be the beneficial owner of more than 5% of our common stock outstanding, (ii) each of our directors and named executive officers, and (iii) all of our directors and executive officers as a group.

Name and Address of Beneficial Owner (1)	Shares Beneficially Owned (2)	
	Number	Percent
BlackRock, Inc. and affiliates (3) 55 East 52nd Street New York, NY 10055	14,288,924	16.50%
Altiya Management Inc. and affiliates (4) 1055b Powers Place Alpharetta, GA 30009	10,111,733	11.68%
Farallon Capital Management LLC (5) One Maritime Plaza Suite 2100 San Francisco, CA 94111	8,250,000	9.53%
Vanguard Group Inc.(6) PO Box 2600 V26 Valley Forge PA 19482-2600	5,703,951	6.59%
T. Rowe Price Associates, Inc.(7) 100 East Pratt Street Baltimore, MD 21202	4,990,790	5.76%
Eagle Asst Management (8) 880 Carillon Parkway St. Petersburg, FL 33716	4,506,284	5.20%
State Street Corporation and affiliates (9) One Lincoln Street Boston MA 02111	4,395,011	5.08%
David W. Mims (10)	16,393	*
Gerard Ber (11)	66,393	*
Bradley L. Campbell (12)	110,000	*
Eric J. Ende (13)	16,393	*
Karen J. Ferrante (14)	170,000	*
Ann MacDougall (15)	36,065	*
Heinz Mausli (16)	16,393	*
Asha Das (17)	25,000	*
Patrick Fabbio (18)	358,500	*
Benedict Osorio (19)	91,452	*
Vivien Wong (20)	635,421	*
Mark R. Baker (21)	-	*
All directors and executive officers as a group (22)	1,542,010	1.75%

* Less than one percent.

(1) The address of each beneficial owner who is a director or officer of the Company is in care of the Company.

(2) With respect to our directors and executive officers, and except as indicated and/or pursuant to applicable community property laws, each stockholder possesses sole voting and investment power with respect to the shares of common stock listed. The number of shares of common stock beneficially owned includes shares issuable pursuant to stock options held by the stockholder that are currently exercisable (i.e., within 60 days of March 2, 2020). Shares issuable upon exercise of these options are deemed outstanding for computing the percentage of beneficial ownership of the person holding the options but not of any other person. None of the shares held by our directors and executive officers are pledged as collateral.

With respect to other stockholders identified above, the percent reported is calculated by dividing (i) the number of shares reported by the stockholder in the Schedule 13G or Schedule 13D filing described in the related note by (ii) the aggregate number of our common shares outstanding on March 2, 2020, and differs from the Percent of Class reported in the stockholder's Schedule 13G or Schedule 13D; it assumes that the stockholder continued to own the number shares reported in its Schedule 13G or Schedule 13D on March 2, 2020.

- (3) Based on a Schedule 13G (Amendment No. 7) filed on February 4, 2020, BlackRock Advisors, LLC, BlackRock Investment Management (UK) Limited, BlackRock Asset Management Canada Limited, BlackRock (Netherlands) B.V., BlackRock Fund Advisors, BlackRock Asset Management Ireland Limited, BlackRock Institutional Trust Company, National Association, BlackRock Financial Management, Inc., BlackRock Asset Management Schweiz AG and BlackRock Investment Management, LLC acquired the securities reported. According to the Schedule 13G, BlackRock, Inc., in its capacity as a parent-holding company of the foregoing BlackRock funds, has sole voting power over 14,128,367 shares of our common stock and sole dispositive power over 14,288,924 shares of our common stock.
- (4) Based on a Schedule 13D (Amendment No. 4) filed on November 12, 2019, Altiva Management Inc., Velan Capital, L.P., Balaji Venkataraman, Dr. Virinder Nohria, LTE Partners, LLC, LTE Management, LLC, Melkonian Capital Management, LLC and Ryan Melkonian acquired the securities reported. According to the Schedule 13D, Velan Capital, L.P., Altiva Management Inc., as general partner of Velan Capital, L.P., and Balaji Venkataraman, as the sole shareholder of Altiva Management Inc., have sole voting and dispositive power over 8,011,733 shares of our common stock, Dr. Virinder Nohria has sole voting and dispositive power over 110,000 shares of our common stock, and LTE Partners, LLC, LTE Management, LLC, Melkonian Capital Management, LLC and Ryan Melkonian have sole voting and dispositive power over 1,950,000 shares of our common stock.
- (5) Based on a Schedule 13G (Amendment No. 1) filed on February 14, 2020, Farallon Capital Management LLC and affiliates acquired the securities reported. According to the Schedule 13G, Farallon Capital Management LLC and affiliates have shared voting and dispositive power over the 8,250,000 shares of our common stock.
- (6) Based on a Schedule 13G filed on February 11, 2020, Vanguard Group, Inc. acquired the securities reported. According to the Schedule 13G, Vanguard Group, Inc. has sole voting power over 183,921 shares of our common stock, shared voting power over 6,252 shares of our common stock, sole dispositive power over 5,523,835 shares of our common stock and shared dispositive power over 180,116 shares of our common stock.
- (7) Based on a Schedule 13G filed on February 14, 2020, T. Rowe Price Associates, Inc. acquired the securities reported. According to the Schedule 13G, T. Rowe Price Associates, Inc. has sole voting power over 781,244 shares of our common stock and sole dispositive power over 4,990,790 shares of our common stock.
- (8) Based on a Schedule 13G (Amendment No. 4) filed on January 6, 2020, Eagle Asset Management, Inc. acquired the securities reported. According to the Schedule 13G, Eagle Asset Management, Inc. has sole voting and dispositive power over the 4,506,284 shares of our common stock.
- (9) Based on a Schedule 13G filed on February 13, 2020, SSGA Funds Management, Inc., State Street Global Advisors Limited (UK), State Street Global Advisors, Australia Limited and State Street Global Advisors Trust Company acquired the securities reported. According to the Schedule 13G, State Street Corporation, in its capacity as a parent-holding company of the foregoing State Street funds, has shared voting power over 4,077,410 shares of our common stock and has shared dispositive power over the 4,395,011 shares of our common stock.
- (10) Consists of 16,393 shares issuable upon exercise of currently exercisable options.
- (11) Includes 50,000 shares outstanding and 16,393 issuable upon exercise of currently exercisable options.
- (12) Includes 12,000 shares outstanding and 98,000 issuable upon exercise of currently exercisable options.
- (13) Consists of 16,393 shares issuable upon exercise of currently exercisable options.
- (14) Consists of 170,000 shares issuable upon exercise of currently exercisable options.
- (15) Consists of 36,065 shares issuable upon exercise of currently exercisable options.
- (16) Consists of 16,393 shares issuable upon exercise of currently exercisable options.
- (17) Consists of 25,000 shares issuable upon exercise of currently exercisable options.
- (18) Consists of 358,500 shares issuable upon exercise of currently exercisable options.
- (19) Includes 21,202 shares outstanding and 70,250 issuable upon exercise of currently exercisable options.
- (20) Includes 4,121 shares outstanding and 631,300 issuable upon exercise of currently exercisable options.
- (21) Mr. Baker resigned as director and CEO of the Company effective November 11, 2019.
- (22) Includes 87,323 shares outstanding and 1,454,687 issuable upon exercise of currently exercisable options held by directors, NEOs, and other executive officers of the Company.

Equity Compensation Plan Information

The following table sets forth certain information related to our equity compensation plans as of December 31, 2019.

	Number of shares to be issued upon exercise of outstanding options(1)	Weighted average exercise price of outstanding options	Number of shares remaining available for future issuance (excluding securities reflected in first column)(2)
Equity compensation plans approved by stockholders	6,939,672	\$ 6.35	6,680,952
Equity compensation plans not approved by stockholders	-	-	-
Total	6,939,672	\$ 6.35	6,680,952

(1) Of these shares, 5,207,753 were subject to options granted under our 2005 Stock Incentive Plan (the “2005 Plan”) and 1,731,919 were subject to options granted under the 2018 Plan. No awards other than stock options were outstanding under any of our plans.

(2) All of these shares were available for award grant purposes under the 2018 Plan. Subject to certain express limits of the 2018 Plan, shares available under the 2018 Plan generally may be used for any type of award authorized under that plan including options, stock appreciation rights, stock awards, restricted stock and restricted stock units. No new awards will be granted under the 2005 Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

We have entered into indemnification agreements with each of our directors and executive and other officers. These agreements require us to indemnify such individuals to the fullest extent permitted by Delaware law for certain liabilities to which they may become subject as a result of their affiliation with us.

Our Code of Business Ethics and Conduct, which our Corporate Governance Guidelines make applicable to all directors and employees, including our CEO and CFO, requires all Progenics personnel to act in the best interests of the Company consistent with their duty of loyalty to it, including by avoiding situations and relationships that involve actual or potential conflicts of interest. Situations that could be perceived as conflicts of interest include related party transactions. Our Code of Business Ethics and Conduct requires our personnel who believe they are involved in or become aware of a potential conflict of interest to discuss the matter with the individual’s manager and our General Counsel. Our Audit Committee is required and empowered to meet with our management and independent auditors to review all related party transactions that would be required to be disclosed in our annual proxy statement for potential conflicts of interest situations and, on an ongoing basis, approve such transactions. The Audit Committee’s policy is to approve only those transactions that are in the best interests of our stockholders. In addition, our Nominating and Corporate Governance Committee is required and empowered to conduct any and all investigations into alleged violations of our Corporate Governance Guidelines or Code of Business Ethics and Conduct, and present the results of such investigations to our Board.

Director Independence

The Board has determined each of Ms. MacDougall, Messrs. Campbell and Mäusli, and Drs. Ber, Ende and Ferrante to be an “independent director” as such term is defined in Nasdaq Marketplace rules. None of the independent directors of the Company has any relationship, direct or indirect, to us other than as stockholders of the Company or through their service as our directors.

The Board has also determined that each member of the Audit Committee and the Compensation Committee meets the independence standards applicable to those committees prescribed by the Nasdaq Marketplace rules, the SEC and the Internal Revenue Service.

With the assistance of our legal counsel, the Nominating and Corporate Governance Committee reviews the applicable legal standards for Board member and Board committee independence and the criteria applied to determine “audit committee financial expert” status, as well as the answers to annual questionnaires completed by each of our directors. On the basis of this review, the Nominating and Corporate Governance Committee delivered a report to the full Board and the Board made its independence and “audit committee financial expert” determinations based upon the Nominating and Corporate Governance Committee’s report and each member’s review of the information made available to the Nominating and Corporate Governance Committee.

Item 14. Principal Accountant Fees and Services

The following table discloses the fees that EY billed or is expected to bill for professional services rendered to us for 2019 and 2018. There were no audit-related fees billed or expected to be billed during 2019 and 2018.

	2019	2018
Audit Fees (1)	\$ 749,000	\$ 827,876
Tax Fees (2)	\$ 14,698	\$ 16,000
All Other Fees (3)	\$ 2,000	\$ 1,595

(1) In connection with (i) the audit of our annual financial statements, including attestation services required under section 404 of the Sarbanes-Oxley Act of 2002, and reviews of quarterly interim financial statements (\$689,000 in 2019 and \$717,876 in 2018) and (ii) the filing of a replacement shelf registration statement on Form S-3 with the SEC and issuance of comfort letters for at-the-market transactions (\$60,000 in 2019 and \$110,000 in 2018).

(2) In connection with tax consultation services for the IRC Section 382 analysis (\$14,698 for 2019 and \$16,000 for 2018).

(3) For proprietary internet-based services (\$2,000 in 2019 and \$1,595 in 2018).

Pre-Approval of Audit and Non-Audit Services by the Audit Committee

Audit and non-audit services performed for us by our independent registered public accounting firm must be pre-approved by the Audit Committee in order to assure that the provision of such services does not impair the accounting firm's independence. During the first quarter of each year, the Audit Committee reviews a schedule prepared by the accounting firm of certain types of services to be provided for that year along with projected fees. The Audit Committee reviews the schedule and provides general pre-approval of those types of services. The fee amounts are updated to the extent necessary at regularly scheduled meetings of the Audit Committee. Any additional service proposed to be provided after the annual pre-approval process requires specific pre-approval by the Audit Committee. The Audit Committee may delegate either general or specific pre-approval authority to its chair or any other member(s). The member(s) to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next meeting. The Audit Committee approved all services described above during 2019 and 2018.

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, 2019 and 2018

Consolidated Statements of Operations for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

All financial statement schedules referred to in Item 12-01 of Regulation S-X 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 prior to the signature page of this Report and incorporated herein by reference.

Item 16. Form 10-K Summary

None.

PROGENICS PHARMACEUTICALS, INC.
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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, 2019 and 2018, 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, 2019, and the related notes (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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 13, 2020 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for operating leases on January 1, 2019 due to the adoption of ASU No. 2016-02, *Leases*.

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 13, 2020

PROGENICS PHARMACEUTICALS, INC.

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

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 42,049	\$ 137,686
Accounts receivable, net	15,976	3,803
Other current assets	5,707	2,640
Total current assets	63,732	144,129
Property and equipment, net	11,688	3,944
Intangible assets, net	6,823	6,666
Goodwill	17,847	13,074
Operating right-of-use lease assets	13,493	-
Other assets	5,887	1,684
Total assets	\$ 119,470	\$ 169,497
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,249	\$ 444
Accrued expenses	13,103	10,533
Contingent consideration liability	-	7,050
Current portion of debt, net	7,117	5,419
Operating lease liabilities	599	-
Total current liabilities	22,068	23,446
Long-term debt, net	31,910	39,180
Operating lease liabilities	15,005	-
Contingent consideration liability	3,900	3,950
Deferred tax liability	34	28
Other liabilities	-	1,818
Total liabilities	72,917	68,422
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 - 86,760 shares in 2019 and 84,742 shares in 2018	113	110
Additional paid-in capital	727,089	713,019
Treasury stock at cost, 200 shares of common stock	(2,741)	(2,741)
Subscription receivable	-	-
Accumulated other comprehensive loss	(148)	(105)
Accumulated deficit	(677,760)	(609,208)
Total stockholders' equity	46,553	101,075
Total liabilities and stockholders' equity	\$ 119,470	\$ 169,497

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,		
	2019	2018	2017
Revenues:			
Product sales	\$ 1,559	\$ -	\$ -
Royalty income	16,970	14,908	10,965
License and other revenue	16,457	714	733
Total revenue	34,986	15,622	11,698
Operating expenses:			
Cost of goods sold	3,168	-	-
Research and development	49,223	35,147	42,589
Selling, general and administrative	47,838	29,431	24,909
Intangible impairment charge	-	23,200	-
Change in contingent consideration liability	916	(5,800)	2,600
Total operating expenses	101,145	81,978	70,098
Operating loss	(66,159)	(66,356)	(58,400)
Other (expense) income:			
Interest (expense) income and other income, net	(2,376)	(2,933)	(4,285)
Total other (expense) income	(2,376)	(2,933)	(4,285)
Loss before income tax (expense) benefit	(68,535)	(69,289)	(62,685)
Income tax (expense) benefit	(17)	1,632	11,672
Net loss	<u>\$ (68,552)</u>	<u>\$ (67,657)</u>	<u>\$ (51,013)</u>
Net loss per share - basic and diluted	<u>\$ (0.80)</u>	<u>\$ (0.87)</u>	<u>\$ (0.73)</u>
Weighted-average shares - basic and diluted	<u>85,607</u>	<u>77,890</u>	<u>70,284</u>

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

PROGENICS PHARMACEUTICALS, INC.**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
(In thousands)

	Years Ended December 31,		
	2019	2018	2017
Net loss	\$ (68,552)	\$ (67,657)	\$ (51,013)
Other comprehensive loss:			
Foreign currency translation adjustments	(43)	(72)	52
Comprehensive loss	\$ (68,595)	\$ (67,729)	\$ (50,961)

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

PROGENICS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Accumulated											
	Common Stock		Common Stock		Additional Paid-in	Accumulated	Other Comprehensive	Subscription	Treasury Stock		Total Stockholders'	
	Number	Par	Number	Par Value					Number	Cost		Equity
	of Shares	Value	of Shares	Par Value					Capital	Deficit		Loss
Balance at January 1, 2017	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	
Net loss	-	-	-	-	-	(68,552)	-	-	-	-	(68,552)	
Foreign currency translation adjustment	-	-	-	-	-	-	(43)	-	-	-	(43)	
Stock-based compensation expense	-	-	-	-	4,392	-	-	-	-	-	4,392	
Issuance of common stock to MIP Shareholders	1,632	2	-	-	7,737	-	-	-	-	-	7,739	
Exercise of stock options	386	1	-	-	1,941	-	-	-	-	-	1,942	
Balance at December 31, 2019	86,760	\$ 113	-	\$ -	\$ 727,089	\$ (677,760)	\$ (148)	\$ -	(200)	\$ (2,741)	\$ 46,553	

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,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	\$ (68,552)	\$ (67,657)	\$ (51,013)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	4,392	5,209	4,142
Depreciation and amortization	2,366	1,497	1,121
Non-cash interest expense	271	302	247
Deferred income tax	6	(1,548)	(11,435)
Other	11	-	(3)
Intangible impairment charge	-	23,200	-
Change in fair value of contingent consideration liability	916	(5,800)	2,600
Changes in assets and liabilities:			
Accounts receivable	(12,176)	204	892
Other current assets	(2,898)	(403)	2,046
Other assets	(2,035)	(150)	468
Accounts payable	808	(2,906)	2,779
Accrued expenses	2,612	1,009	(6,274)
Other current liabilities	80	-	-
Other liabilities	(499)	291	323
Net cash used in operating activities	(74,698)	(46,752)	(54,107)
Cash flows from investing activities:			
Acquisition of AZEDRA manufacturing assets	(8,000)	-	-
Purchases of property and equipment	(7,231)	(817)	(269)
Portion of MIP milestones paid to former advisor	(277)	-	-
Proceeds from sale of fixed assets	-	-	37
Net cash used in investing activities	(15,508)	(817)	(232)
Cash flows from financing activities:			
Net proceeds from public offering of common stock	-	69,987	-
Net proceeds from issuance of common stock in connection with at-the-market offering	-	29,653	5,026
Repayment of debt	(5,843)	(5,390)	-
Proceeds from exercise of stock options	1,942	467	469
Return of estimated interest payment for noncontrolling interest	-	-	15
Net cash (used in) provided by financing activities	(3,901)	94,717	5,510
Effect of currency rate changes on cash, cash equivalents and restricted cash	(48)	(92)	83
Net decrease in cash, cash equivalents, and restricted cash	(94,155)	47,056	(48,746)
Cash, cash equivalents, and restricted cash at beginning of period	139,220	92,164	140,910
Cash, cash equivalents, and restricted cash at end of period	\$ 45,065	\$ 139,220	\$ 92,164
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 4,131	\$ 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 condensed consolidated balance sheets to the total of the same such amounts shown above for the years ended December 31, 2019 and 2018:

Cash, cash equivalents and restricted cash information

Cash and cash equivalents at beginning of period	137,686	90,642
Restricted cash included in long-term assets at the beginning of period	1,534	1,522
Cash, cash equivalents and restricted cash at beginning of period	\$ 139,220	\$ 92,164
Cash and cash equivalents at end of period	42,049	137,686
Restricted cash included in long-term assets at the end of period	3,016	1,534
Cash, cash equivalents, and restricted cash at end of period	\$ 45,065	\$ 139,220

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

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 enrollment completion of our pivotal phase 3 trial for PyL and the positive topline results. Our pipeline includes therapeutic agents designed to precisely target cancer (AZEDRA, 1095 and PSMA TTC), as well as a prostate-specific membrane antigen (“PSMA”) targeted imaging agents for prostate cancer (PyL and 1404).

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 and commercializing 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 AZEDRA product sales, royalty, development and commercial milestones from Bausch, Bayer and FUJIFILM. 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

The Company is not profitable and there is no assurance that we will ever achieve and sustain profitability on a continuing basis. In addition, development activities, clinical testing, and commercialization of the Company’s product candidates will require additional financing. The Company’s accumulated deficit at December 31, 2019 totaled \$677.8 million, and management expects to incur substantial losses in future periods. The success of the Company is subject to certain risks and uncertainties, including among others, uncertainty of product development and commercialization; uncertainty of capital availability; uncertainty in the Company’s ability to enter into agreements with collaborative partners; dependence on third parties; and dependence on key personnel.

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. 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).

At December 31, 2019, we had \$42.0 million in cash and cash equivalents, a decrease of \$95.7 million from \$137.7 million at December 31, 2018. On February 20, 2020, we announced the signing of an amended and restated definitive merger agreement for the proposed merger of Progenics with Lantheus Holdings. Consistent with regular practice for a growth-stage pharmaceutical or biotechnology company, and as we have done in the past, we anticipate obtaining additional financing in order to meet our cash requirements if the Lantheus Holdings agreement is not ultimately consummated. However, there can be no assurances that we will be able to obtain additional capital on acceptable terms and in the amounts necessary to fully fund our current operating expenses or reduced operating expenses reflecting delays or reductions in the scope of our product development programs beyond one year from the date this annual report is issued. As such, we believe there is substantial doubt regarding our ability to continue as a going concern within one year after the date this Annual Report on Form 10-K is filed with the SEC. The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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, leases 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.

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, 2019, 2018, and 2017.

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

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, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09” or the “Topic 606”), we assess the goods or services promised within each contract for the purpose of identifying them as performance obligations. We must apply judgement in assessing whether each promised good or service is distinct. If a promised good or service is not distinct, we will combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

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

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

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

The following are our revenue streams from contracts with customers for the three years ended December 31, 2019 (in thousands):

	2019	2018	2017
Product sales	\$ 1,559	\$ -	\$ -
Royalty income	16,970	14,908	10,965
License and other revenue	16,457	714	733
Total revenue	\$ 34,986	\$ 15,622	\$ 11,698

Product sales – represent revenue from sales of AZEDRA directly to hospitals. Our performance obligations are to provide AZEDRA based on sales orders from hospitals, which have been verified by our commercial team as properly credentialed to receive, handle, administer and dispose of radioactive materials. We recognize revenue after the customer takes title and has obtained control of the product. Our contracts with hospitals stipulate that product is shipped free on-board destination. We invoice hospitals after the products have been delivered and invoice payments are generally due within 60 days of invoice date. We record sales to hospitals based on AZEDRA's list price per mCi and the amount prescribed based upon a dosimetric assessment of each patient. We record product sales net of any variable consideration due to rebates and discounts provided under governmental and other programs, and other sales-related deductions, such as product returns and copay assistance programs. Shipping and handling costs associated with finished goods delivered to customers are recorded as a selling expense.

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.

License and 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 \$16.5 million license and other revenue for the year ended December 31, 2019, is the \$10.0 million sales milestone we recognized under the RELISTOR License Agreement (achievement of U.S. net sales of RELISTOR in excess of \$100.0 million), \$4.0 million upfront payment from FUJIFILM under the aBSI agreement and \$2.0 million milestone under the Bayer agreement for initiation of a Phase 1 trial of PSMA TTC. We are eligible for future milestone and royalty payments under both license agreements with Bausch and Bayer.

We had receivable contract balances of \$16.0 million and \$3.8 million as of December 31, 2019 and 2018, respectively, primarily related to the royalty revenue stream and milestone payment under our partnership with Bausch (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.

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 Per Share

We prepare earnings per share (“EPS”) data in accordance with ASC 260 (Topic 260, *Earnings Per Share*). Basic net loss per share amounts have been computed by dividing net loss attributable to us by the weighted-average number of common shares outstanding during the period. For 2019, 2018 and 2017, we reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. 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

Comprehensive loss 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 includes net loss adjusted for the changes in foreign currency translation adjustment. The disclosures required by ASC 220 (Topic 220, *Comprehensive Income*) for 2019, 2018, and 2017 have been included in the consolidated statements of comprehensive loss. There was no income tax expense/benefit allocated to any component of other comprehensive loss (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, 2019 and 2018, we had invested approximately \$35.8 million and \$136.1 million, respectively, in cash equivalents in the form of money market funds with two investment companies and held approximately \$6.2 million and \$1.6 million, respectively, in three commercial banks.

Restricted Cash

Restricted cash included in long-term assets of \$3.0 million and \$1.5 million at December 31, 2019 and 2018, respectively, represents collateral for a letter of credit securing a lease obligation (for both periods), collateral for a letter of credit related to equipment purchases and a security deposit with the German District Court related to the PSMA-617 litigation (for 2019). 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, 2019 and 2018, we had no allowance for doubtful accounts.

Leases

We determine whether an arrangement is or contains a lease at its inception. We recognize lease liabilities based on the present value of the minimum lease payments not yet paid by using the lease term and discount rate determined at lease commencement. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate to determine the present value of our lease payments. Our leases may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. We recognize the operating right-of-use ("ROU") lease assets at amounts equal to the lease liability adjusted for prepaid or accrued rent, remaining balance of any lease incentives and unamortized initial direct costs.

The operating lease liabilities are reported in other current liabilities and other noncurrent liabilities and the related ROU lease assets are reported in other noncurrent assets on our condensed consolidated balance sheets. Lease expense for our operating leases is calculated on a straight-line basis over the lease term and is reported in research and development and selling, general and administrative expenses on our condensed consolidated statements of operations. We do not recognize a lease liability or ROU lease assets for leases whose lease terms, at commencement, are twelve months or less, or for leases which are below the established capitalization threshold.

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, 2019 or 2018.

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 those 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.

Recurring Fair Value Measurements

We believe the carrying amounts of our cash equivalents, accounts receivable, other current assets, other assets, accounts payable, accrued expenses, and current portion of our debt approximated their fair values as of December 31, 2019 and 2018 due to their short term nature. The estimated fair value of our non-recourse royalty-backed long-term debt (see **Note 9. Non-Recourse Long-Term Debt, Net** for additional information) approximates its carrying value as the interest rate is in line with the market interest rates for this type of debt with the respective underlining collateral value.

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 acquired in a business combination, 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, 2019 and 2018.

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 or at fair value for assets acquired in a business combination. 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
Furniture and fixtures (in years)	5
Leasehold improvements	Earlier of life of improvement or lease

Deferred Lease Liability and Incentive

Prior to the adoption of ASU 2016-02 on January 1, 2019, for our lease agreements that included fixed escalations of minimum annual lease payments, we recognized rental expense on a straight-line basis over the lease terms and recorded the difference between rent expense and current rental payments as deferred lease liability. Deferred lease incentive included a construction allowance from our landlord which was amortized as a reduction to rental expense on a straight-line basis over the lease term. As of December 31, 2018, our consolidated balance sheet included the following:

	2018
Other current liabilities:	
Deferred lease incentive	\$ 26
Other liabilities:	
Deferred lease liability	\$ 1,541
Deferred lease incentive	\$ 277

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).

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 2019, 2018, and 2017, the primary sources of our revenues were AZEDRA product sales, royalty and milestone payments. There can be no assurance that such revenues will continue. Substantially all of our accounts receivable at December 31, 2019 and 2018 were from the above-named sources.

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 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 lease assets and lease 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.

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.
- ASU No. 2019-01, *Leases (Topic 842): Codification Improvements*.

We adopted 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 and did not adjust comparative periods. We also elected the package of practical expedients permitted under this standard, which among other things, allowed us to carry forward the lease classification for our existing leases. In preparation for the adoption of this standard and to enable preparation of the required financial information, we implemented new internal controls and processes.

The adoption of this standard impacted our 2019 opening consolidated balance sheet as we recorded operating lease liabilities of \$15.3 million and ROU lease assets of \$13.5 million, which equals the lease liabilities net of deferred rent and lease incentives previously recorded on our balance sheet under the old guidance. The adoption of this standard did not have an impact on our consolidated statements of operations or cash flows.

Recently Issued

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.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* and in April 2019, the FASB issued ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, which amend the scope and transition requirements of ASU 2016-13. The standard requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions and reasonable and supportable forecasts that affect the collectability of the reported amount. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*. This ASU addresses certain stakeholders’ concerns by providing an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For those entities, the targeted transition relief will increase comparability of financial statement information by providing an option to align measurement methodologies for similar financial assets. Furthermore, the targeted transition relief also may reduce the costs for some entities to comply with the amendments in Update 2016-13 while still providing financial statement users with decision-useful information. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Date*. This ASU extended and simplified how effective dates are staggered between larger public companies (bucket one) and all other entities (bucket two). ASU 2016-13 is effective for SEC filers, excluding entities eligible to be smaller reporting companies, for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 and beginning after December 15, 2020 for all other public business entities. We are currently evaluating the impact this guidance will have on our consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements.

3. Somerset Acquisition, Goodwill, In-Process Research and Development and Other Intangible Assets

Somerset Acquisition

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 manufacturing facility for AZEDRA and will also provide manufacturing support for the Company’s development stage radiopharmaceuticals, including 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.

Purchase Price Allocation: We accounted for this acquisition as a business combination by allocating the consideration we paid to the fair values of the assets acquired at the effective date of the acquisition, as summarized below. The difference between the fair value of the acquisition consideration and the estimated fair value of the identifiable assets represents potential future economic benefits arising from the acquisition, and has been recorded as goodwill.

The following table summarizes the allocation of the consideration paid to the estimated fair values of the assets acquired as of the acquisition date (in thousands):

	Amount
Cash consideration	\$ 8,000
Tangible assets acquired:	
Machinery and equipment	682
Leasehold improvements	1,300
Total tangible assets acquired	1,982
Intangible assets - Somerset	1,245
Total tangible and intangible assets acquired	3,227
Goodwill	\$ 4,773

The replacement cost method, a variation of the cost approach, was applied to assess the value of the assets acquired by Progenics. The principle behind this method is that the value represents the current cost of a similar new asset having the nearest equivalent utility as the asset being valued. It generally represents the maximum amount that a prudent investor will pay for a comparable asset. The cost approach provides a systematic framework for estimating the value of tangible or intangible assets based on the economic principle of substitution, and that no prudent investor will purchase an existing asset for more than it will cost to create a comparable asset. Under this approach, value is estimated by developing the cost to either replace or reproduce (replicate) the asset of similar utility.

The acquired Somerset intangible assets represent manufacturing know-how, which is comprised of documented technical data and information, formulae, standards, specifications, processes, methods, code books, as well as all information, knowledge, trade practices and secrets utilized by the Somerset facility in manufacturing of the AZEDRA. We estimate the remaining useful life of the Somerset intangible to be approximately six years.

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

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

The following table summarizes the activity related to goodwill and intangible assets (in thousands):

	Goodwill	IPR&D	Other Intangible Assets
Balance at January 1, 2018	\$ 13,074	\$ 28,700	\$ 1,669
Reclassification of AZEDRA IPR&D	-	(4,900)	4,900
Impairment of 1404 IPR&D	-	(23,200)	-
Amortization expense	-	-	(503)
Balance at December 31, 2018	13,074	600	6,066
Increase related to Somerset acquisition	4,773	-	1,245
Amortization expense	-	-	(1,088)
Balance at December 31, 2019	\$ 17,847	\$ 600	\$ 6,223

The following table reflects the components of the finite-lived intangible assets as of December 31, 2019 (in thousands):

	Gross Amount	Accumulated Amortization	Net Carrying Value
Intangible assets - AZEDRA product rights	\$ 4,900	\$ 992	\$ 3,908
Intangible assets - Somerset	1,245	176	1,069
Intangible assets - EXINI technology	2,120	874	1,246
Total	\$ 8,265	\$ 2,042	\$ 6,223

The weighted-average remaining life of the finite-lived intangible assets was approximately six years at December 31, 2019.

Amortization expense was calculated on a straight-line basis over the estimated useful life of the asset and was \$1.1 million, \$0.5 million and \$0.2 million per year for the years ended December 31, 2019, 2018 and 2017, 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 \$1.1 million in each of the next five years (2020 through 2024) and \$0.7 million in 2025.

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, 2019			
	Balance at December 31, 2019	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		(Level 1)	(Level 2)	(Level 3)
Assets:				
Money market funds	\$ 35,775	\$ 35,775	\$ -	\$ -
Total assets	\$ 35,775	\$ 35,775	\$ -	\$ -
Liabilities:				
Contingent consideration liability	\$ 3,900	\$ -	\$ -	\$ 3,900
Total liabilities	\$ 3,900	\$ -	\$ -	\$ 3,900

	Balance at December 31, 2018	Fair Value Measurements at December 31, 2018		
		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		(Level 1)	(Level 2)	(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

The contingent consideration liability of \$3.9 million and \$11.0 million at December 31, 2019 and 2018, 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 and/or from proceeds received from license revenue (in thousands):

Program	Consideration	Form of Payment
1095	5,000	Cash or Progenics common stock
1404	9,984	Cash or Progenics common stock or cash in the case of license revenue
	\$ 14,984	

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):

	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.

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, 2019 and 2018 (in thousands). The 2019 decrease in the contingent consideration liability of \$7.1 million was primarily attributable to the \$8.0 million payment for the AZEDRA first commercial sale milestone, which was partially offset by an increase in the AZEDRA sales forecasts associated with a study to expand the label for AZEDRA and a decrease in the discount period used to calculate the present value of the contingent consideration liability. 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.

	Fair Value at December 31, 2019	Valuation Technique	Unobservable Input	Assumption
Contingent Consideration Liability:				
1095 commercialization	\$ 500	Probability adjusted discounted	Probability of success	18%
		cash flow model	Period of expected milestone achievement	2026
			Discount rate	10%
1404 commercialization	300	Probability adjusted discounted	Probability of success	43%
		cash flow model	Period of expected milestone achievement	2022 - 2035
			Discount rate	10
Net sales targets	3,100	Monte-Carlo simulation	Probability of success	18% - 90%
			Discount rate	10
Total	\$ 3,900			

	Fair Value at December 31, 2018	Valuation Technique	Unobservable Input	Assumption
Contingent Consideration Liability:				
AZEDRA commercialization	\$ 7,050	Probability adjusted discounted	Probability of success	90%
		cash flow model	Period of expected milestone achievement	2019
			Discount rate	10%
1095 commercialization	450	Probability adjusted discounted	Probability of success	18%
		cash flow model	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			

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

	Liability - Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	2019	2018
Balance at beginning of period	\$ 11,000	\$ 16,800
Fair value change included in net loss	916	(5,800)
Payments	(8,016)	-
Balance at end of period	\$ 3,900	\$ 11,000
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	\$ 916	\$ (5,800)

5. Accounts Receivable

Our accounts receivable represent amounts due to us primarily from royalties, collaborators, milestone payments and AZEDRA product sales, and consisted of the following at December 31, 2019 and 2018 (in thousands):

	2019	2018
Royalties	\$ 4,304	\$ 3,151
Product sales, license and other	11,672	652
Accounts receivable, net	\$ 15,976	\$ 3,803

6. Fixed Assets

Fixed assets as of December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
Machinery and equipment	\$ 5,204	\$ 2,992
Leasehold improvements	3,204	1,734
Computer equipment	691	721
Furniture and fixtures	908	878
Construction in progress	5,475	317
Property and equipment, gross	15,482	6,642
Less - accumulated depreciation	(3,794)	(2,698)
Property and equipment, net	\$ 11,688	\$ 3,944

At December 31, 2019 and 2018, \$2.7 million and \$1.5 million, respectively, of net leasehold improvements were being amortized over periods of 10.8 years and 11.8 years, under leases with terms through September 30, 2030. We recorded depreciation expense of \$1.3 million, \$1.0 million, and \$0.9 million during 2019, 2018, and 2017, 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, 2019 and 2018:

	2019	2018
Accrued legal and professional fees	\$ 1,889	\$ 1,305
Accrued payroll and related costs	2,795	2,871
Accrued contract manufacturing costs	5,114	2,516
Accrued clinical trial costs	1,489	2,318
Accrued consulting costs	1,117	862
Other	699	661
Accrued expenses	\$ 13,103	\$ 10,533

8. Commitments and Contingencies

Operating Leases

At December 31, 2019, we leased: (i) corporate office space in New York City, pursuant to a lease agreement expiring in September 2030 (subject to an early termination right), (ii) radiopharmaceutical manufacturing facility located in Somerset, New Jersey under a sublease agreement expiring in November 2028, and (iii) additional office space in Lund, Sweden, pursuant to a lease agreement expiring in December 2021. We also lease certain office equipment under noncancelable operating leases.

Under ASU 2016-02, adopted on January 1, 2019, we determine whether an arrangement is or contains a lease at its inception. We recognize lease liabilities based on the present value of the minimum lease payments not yet paid, by using the lease term and discount rate determined at lease commencement. As our leases do not provide an implicit rate, we use our incremental borrowing rate of 9.5% commensurate with the underlying lease terms to determine the present value of our lease payments. Rental payments are recognized as rent expense on a straight-line basis over the term of the lease and for the year ended December 31, 2019, we recognized rent expense in the amount of \$2.3 million. Our leases have remaining lease terms of one year to 11 years, one of which includes an option to extend the lease for five years. For the year ended December 31, 2019, cash payments against operating lease liabilities totaled \$2.0 million.

The information related to our leases as of December 31, 2019 is as follows (in thousands):

Operating leases	December 31, 2019
Operating ROU lease assets, noncurrent	\$ 13,493
Operating lease liabilities, current	599
Operating lease liabilities, noncurrent	15,005

As of December 31, 2019, future minimum annual payments under all operating lease agreements are as follows:

Years ending December 31,	Minimum Annual Payments
2020	\$ 2,040
2021	2,076
2022	2,213
2023	2,255
2024	2,297
Thereafter	14,510
Total future minimum lease payments	25,391
Less imputed interest	(9,787)
Total lease liabilities	\$ 15,604

Before the adoption of ASU 2016-02, rental expense totaled approximately \$1.9 million and \$1.9 million for 2018 and 2017, respectively. For 2018 and 2017, rent expense exceeded amounts paid by \$0.3 million and \$0.3 million, respectively.

Additional facility charges, including utilities, taxes, and operating expenses, were approximately \$0.1 million per year for 2019, 2018, and 2017.

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 \$0.4 million, \$0.5 million, and \$0.3 million during 2019, 2018, and 2017, respectively.

	Paid from inception/acquisition to December 31, 2019	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	\$ 504	\$ 52,188	Annual minimum royalty payments and milestones to use technology related to PSMA.
Selexis Commercial License Agreement	\$ 124	\$ 1,824	Milestones and royalties to use Selexis technology related to PSMA Antibodies.
University of Zurich and the Paul Scherrer Institute	\$ 590	\$ 925	Annual maintenance and license fee payments, milestones and royalties in respect of licensed technology related to 1404.
University of Western Ontario 2003 Agreement	\$ 41	\$ 151	Annual minimum royalty, administration and milestone payments in respect of licensed technology related to AZEDRA.
Johns Hopkins University Technology	\$ 435	\$ 2,500	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 \$5.1 million through December 31, 2019, 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 \$0.2 million, \$0.3 million, and \$0.3 million for 2019, 2018, and 2017, 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

Paragraph IV Certifications - Mylan

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.

Paragraph IV Certification – Actavis

On or about October 27, 2015, January 5, 2016, and January 8, 2016, Progenics, Salix and Wyeth received three separate notifications of a Paragraph IV certification for certain patents for RELISTOR (methylnaltrexone bromide) subcutaneous injection, for certain patents that are listed in the FDA’s Orange Book. The certifications resulted from the filing by Actavis LLC of an ANDA with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

District Court Actions

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

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

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

The 2:17-cv-06714-SRC-CLW and 2:17-cv-07206-SRC-CLW were consolidated into a single action in the District of New Jersey (2:17-cv-06714-SRC-CLW). Litigation in 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.

Settlement Agreement - Actavis

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

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

Federal Circuit Appeal

On May 25, 2018, Mylan filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit (“CAFC”). 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 has concluded. Mylan submitted its opening brief on April 9, 2019. Plaintiffs filed their responsive brief on July 2, 2019. Mylan filed its reply brief on August 6, 2019. Oral argument was held February 4, 2020. We await the decision from the CAFC which we anticipate in a few months.

Paragraph IV Certification - Par

On or about July 15, 2017, Progenics, Salix and Wyeth received notification of a Paragraph IV certification for RELISTOR (methylglutathione bromide) subcutaneous injection, for certain patents that are listed in the FDA’s Orange Book. The certification resulted from the filing by Par Sterile Products, LLC (“Par Sterile”) of an ANDA with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

District Court Actions

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

Progenics, Salix, Bausch, and Wyeth filed suit against Par Sterile Products, Par Pharmaceutical, and Endo International plc in the Southern District of New York on August 25, 2017 (1:17-cv-06557-PAE) seeking declaratory judgment of infringement of U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, 9,180,125, and 9,669,096 based upon Par Sterile Product’s filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR vials before some or all of these patents expire. This action was voluntarily dismissed on November 30, 2017.

Settlement Agreement - Par

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

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

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

RELISTOR Tablets - Actavis

Paragraph IV Certifications

On or about October 24, 2016 and October 24, 2017, Progenics, Salix, Bausch and Wyeth received two separate notifications of a Paragraph IV certification for RELISTOR (methylbuprenorphine hydrochloride) 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, 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, 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). A four day bench trial was held from May 6, 2019 through May 9, 2019. On July 17, 2019, the Court issued an Order finding the asserted claims of U.S. Patent No. 8,524,276 valid and infringed. The Court additionally ordered that the effective date of any approval of Actavis’s ANDA No. 209615 may not be earlier than the expiration date of U.S. Patent No. 8,524,276.

Progenics, Salix, Bausch, and Wyeth filed suit against Actavis, Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. in the District of New Jersey on June 13, 2019 (2:19-cv-13722-SRC-CLW) seeking declaratory judgment of infringement of U.S. Patent No. 10,307,417 based upon Actavis’s filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before this patent expires. Litigation in the 2:19-cv-13722-SRC-CLW action is not yet underway.

Federal Circuit Appeal

Actavis filed an appeal of the District Court decision with the Court of Appeals for the Federal Circuit on August 13, 2019. The matter is currently pending on appeal at the Federal Circuit and merits briefing is underway. Actavis’s opening brief was filed February 6, 2020.

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 methylaltrexone. 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. Oral proceedings for EP1615646 are set to occur on September 22, 2020. Oral proceedings for EP2368554 and EP2368553, scheduled for March 9 and March 10, 2020, respectively were cancelled by the Board of Appeals on March 9th due to health concerns. We await a communication from the EPO as to how they intend to proceed.

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 patent applications filed worldwide 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 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) 3038996 A1 (EP 14799340.6) and of the Divisional Applications EP 18172716.5, EP 18184296.4, and EP 18203547.7 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. 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; 15/805,900; 16/038,729 and 16/114,988). 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. On November 12, 2019, the University filed a statement with the USPTO to dispute the Confirmation of Ownership filed by MIP.

On February 27, 2019, the German District Court set €416,000 as the amount MIP must deposit with the Court as security in the event of an unfavorable final decision on the merits of the dispute. On February 28, 2019, the Court set a hearing date of August 6, 2019 at which time it held the first oral hearing in the case. The Court considered procedural matters and granted the parties the right to make further submissions. MIP’s further submission was timely filed by the October 1, 2019 deadline. The University filed a reply brief on January 31, 2020, and the Court has scheduled a second oral hearing for May 5, 2020.

Third Party Patents

Post-Grant Review of U.S. Patent No. 10,112,974

On July 29, 2019 we filed a petition for post-grant review (“PGR”) with the United States Patent and Trademark Office (“USPTO”) of U.S. Patent No. 10,112,974 (“the ‘974 patent”), which is jointly owned by Max-Planck-Gesellschaft zur Foerderung der Wissenschaften and Universitat zu Koln (“the Patent Owners”). Certain claims of the ‘974 patent recite precursor compounds for preparing prostate-specific membrane antigen (PSMA) targeting conjugates. In our petition, we allege that such precursor compounds were previously disclosed in other publications, and that certain claims are therefore invalid.

On August 13, 2019, the USPTO mailed a Notice of Filing Date, setting a three (3)-month deadline for the Patent Owners to file a preliminary response. The Patent Owners did not file a response. On January 29, 2020, the Patent Trial & Appeal Board (PTAB) at the USPTO instituted post-grant review of the ‘974 patent, setting a deadline of April 22, 2020 for the Patent Owners to file a response. A final written decision is expected by January 29, 2021.

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, 2019, 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.

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

Condensed Consolidated Balance Sheets	December 31,	
	2019	2018
Outstanding principal balance, current portion	\$ 7,349	\$ 5,688
Unamortized debt discount, current portion	(232)	(269)
Current portion of debt, net	\$ 7,117	\$ 5,419
Outstanding principal balance, long-term portion	\$ 32,170	\$ 39,674
Unamortized debt discount, long-term portion	(260)	(494)
Long-term debt, net	\$ 31,910	\$ 39,180

Condensed Consolidated Statements of Operations	December 31,	
	2019	2018
Interest expense	\$ 4,131	\$ 4,660
Non-cash interest expense	271	302
Total interest expense included in interest (expense) income, net	\$ 4,402	\$ 4,962

Future principal payments, based upon estimated sales projections, under the Royalty-Backed Loan as of December 31, 2019, are as follows:

2020	\$ 7,349
2021	13,162
2022	19,008
Total payments	\$ 39,519

Interest expense, including amortization of debt discount, related to the Royalty-Backed Loan for the year ended December 31, 2019, 2018 and 2017 was approximately \$4.4 million, \$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 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, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at January 1, 2019	6,264	\$ 6.79	6.02
Granted	2,060	\$ 4.78	
Cancelled	(921)	\$ 6.35	
Exercised	(386)	\$ 5.03	
Expired	(77)	\$ 6.22	
Outstanding at December 31, 2019	6,940	\$ 6.35	6.09
Exercisable at December 31, 2019	4,660	\$ 6.65	4.77
Vested and expected to vest at December 31, 2019	6,440	\$ 6.43	5.86

The weighted average fair value of options granted during 2019, 2018, and 2017 was \$3.05, \$4.56, and \$6.96 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 \$1.2 million, \$0.5 million and \$1.0 million, respectively, as of December 31, 2019. The total intrinsic value for stock options exercised during 2019, 2018, and 2017 was \$0.3 million, \$0.2 million, and \$0.2 million, 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.

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 2019, 2018, and 2017:

	2019	2018	2017
Risk-free interest rate	2.35%	2.72%	2.17%
Expected life (in years)	6.73	6.67	6.76
Expected volatility	66%	69%	72%
Expected dividend yield	--	--	--

Stock-based compensation expense for the years ended December 31, 2019, 2018, and 2017 was recorded in our consolidated statement of operations as follows (in thousands):

	2019	2018	2017
Research and development expenses	\$ 1,770	\$ 1,760	\$ 1,371
Selling, general and administrative expenses	2,622	3,449	2,771
Total stock-based compensation expense	\$ 4,392	\$ 5,209	\$ 4,142

At December 31, 2019, unrecognized stock-based compensation expense related to stock options was approximately \$4.1 million and is expected to be recognized over a weighted average period of approximately 2.6 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, 2019, 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 \$0.5 million, \$0.4 million, and \$0.3 million to the 401(k) Plan for the years ended December 31, 2019, 2018, and 2017, 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.

In 2019, we recorded an income tax expense of approximately \$0.02 million as a result of the change in the temporary difference between carrying amounts of in process research and development assets for financial reporting purposes and the amounts used for income tax purposes. Our effective tax rate for 2019 was -0.03%. Since the company has tax basis in goodwill and indefinite-lived intangibles they were excluded from the valuation allowance and had an immaterial tax provision impact. In February 2019, the company acquired AZEDRA manufacturing assets in Somerset in an asset deal resulting in the same book and tax basis and no deferred tax assets or liabilities were recorded. In 2018, we recorded an income tax benefit of approximately \$1.6 million as a result of the change in the temporary difference between carrying amounts of in process research and development assets for financial reporting purposes and the amounts used for income tax purposes. 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%.

We have completed calculations through June 30, 2017, 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, 2017, 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, 2019 consisted of the following:

	2019	2018	2017
Current taxes:			
United States	\$ -	\$ (2)	\$ 3
Foreign	-	-	-
State	11	(82)	(16)
Total current taxes	<u>\$ 11</u>	<u>\$ (84)</u>	<u>\$ (13)</u>
Deferred taxes:			
United States	\$ 9	\$ (1,188)	\$ (8,777)
Foreign	-	-	-
State	(3)	(360)	(2,882)
Total deferred taxes	<u>\$ 6</u>	<u>\$ (1,548)</u>	<u>\$ (11,659)</u>
(Benefit from) provision for income taxes	<u>\$ 17</u>	<u>\$ (1,632)</u>	<u>\$ (11,672)</u>

Deferred tax assets and liabilities as of December 31, 2019 and 2018 consisted of the following:

	2019	2018
Deferred tax assets:		
Research & Experimental and Orphan Drug tax credit carry-forwards	\$ 38,180	\$ 35,435
NYS investment tax credit carry-forwards	929	1,282
Net operation loss carry-forwards	200,738	188,588
Capitalized research and development expenditures	-	1,066
Stock compensation	5,365	5,236
Section 163j disallowed interest	1,243	695
Lease liability	3,380	-
Other items	743	124
Total gross deferred tax assets	250,578	232,426
Less valuation allowance	(246,297)	(232,174)
Deferred tax assets	4,281	252
Deferred tax liabilities:		
Indefinite-lived intangibles	(195)	(136)
Right-of-use lease asset	(2,964)	-
Depreciation and amortization	(1,156)	(144)
Deferred tax liabilities	(4,315)	(280)
Net deferred tax liability	<u>\$ (34)</u>	<u>\$ (28)</u>

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 2019 and 2018, we incurred net losses for tax purposes. We recognized a full tax valuation against deferred tax assets at December 31, 2019 and 2018. In 2019 and 2018, we recognized deferred tax liabilities of \$0.03 million and \$0.03 million, respectively, to reflect the net tax effects of temporary differences between the carrying amounts of in process research and development assets for financial reporting purposes and the amounts used for income tax purposes.

The following is a reconciliation of the U.S. statutory income tax rate to our effective tax rate for the years ended December 31, 2019, 2018, and 2017:

	2019	2018	2017
U.S. Federal statutory rate	21.0%	21.0%	34.0%
State income taxes, net of Federal benefit	0.3%	0.9%	1.5%
Foreign rate differential	0.0%	0.0%	(0.6%)
Research and experimental and Orphan Drug tax credit	3.4%	2.3%	6.4%
Effect of federal and state tax rate changes	(0.4%)	0.3%	(6.1%)
Tax Reform Impact	0.0%	0.0%	13.9%
Change in fair value of contingent consideration liability	(0.3%)	1.8%	(1.4%)
Stock option shortfalls	(0.9%)	(2.2%)	(3.1%)
NOL expiration	(1.2%)	0.0%	0.0%
Other	(1.4%)	(0.5%)	(0.1%)
Change in valuation allowance	(20.5%)	(21.2%)	(25.9%)
Effective tax rate	<u>(0.03%)</u>	<u>2.4%</u>	<u>18.6%</u>

As of December 31, 2019, we had available, for tax return purposes, unused federal NOLs of approximately \$770.0 million, of which \$660.0 million of NOLs generated prior to 2018 will expire in various years from 2020 to 2037 and \$110.0 million of NOLs generated in 2017 can be carried forward indefinitely. Also, we had available, for tax return purposes, unused state NOLs of approximately \$585.8 million, which will expire in various years from 2030 to 2039 and unused foreign NOLs of approximately \$8.5 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, 2019, 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 2000. 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, 2019, 2018, and 2017.

Our R&E and Orphan Drug tax credit carry-forwards of approximately \$38.8 million at December 31, 2019 expire in various years from 2020 to 2039.

As of December 31, 2019, and 2018, 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, 2019 and 2018.

	2019	2018
Beginning uncertain tax benefits	\$ 1,944	\$ 1,951
Prior year - increases (decreases)	-	-
Current year - increases (decreases)	-	-
Settlements	-	-
Expired statutes	(72)	(7)
Ending uncertain tax benefits	<u>\$ 1,872</u>	<u>\$ 1,944</u>

14. Net Loss Per Share

Our basic net loss per share attributable to Progenics amounts have been computed by dividing net loss attributable to Progenics by the weighted-average number of common shares outstanding during the period. For 2019, 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 2019, 2018 and 2017.

For periods when we report net income, 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 per share, basic and diluted, are as follows:

	Net Loss (Numerator)	Weighted-Average Shares Outstanding (Denominator)	Per Share Amount
2019			
Basic and diluted	\$ (68,552)	85,607	\$ (0.80)
2018			
Basic and diluted	\$ (67,657)	77,890	\$ (0.87)
2017			
Basic and diluted	\$ (51,013)	70,284	\$ (0.73)

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 per share:

	2019	2018	2017
Stock options	5,811	3,794	2,395
Contingent consideration liability (1)	766	2,619	2,824
Total securities excluded	6,577	6,413	5,219

(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.

15. Unaudited Quarterly Results (unaudited)

Summarized quarterly financial data during 2019 and 2018 are as follows:

	2019 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	\$ 4,281	\$ 9,966	\$ 5,613	\$ 15,126
Operating expenses	\$ 22,516	\$ 29,059	\$ 23,729	\$ 25,841
Operating loss	\$ (18,235)	\$ (19,093)	\$ (18,116)	\$ (10,715)
Net loss	\$ (18,735)	\$ (19,700)	\$ (18,842)	\$ (11,275)
Net loss per share - basic and diluted	\$ (0.22)	\$ (0.23)	\$ (0.22)	\$ (0.13)

	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)

16. Subsequent Event

On February 20, 2020, we announced the signing of an amended and restated definitive agreement for the proposed merger of Progenics with Lantheus Holdings. The amended agreement reflects the renegotiation of certain of the terms of our original agreement for the proposed merger entered into on October 1, 2019. The combined company would be led by Lantheus Holdings' Chief Executive Officer, Mary Anne Heino. Ms. Heino will be supported by Chief Financial Officer, Robert J. Marshall Jr., and Chief Operations Officer, John Bolla. The definitive agreement provides that, following the closing, Dr. Gérard Ber and Mr. Heinz Mäusli, currently members of Progenics' Board of Directors (the "Board"), will be added as members of the Board of Directors of Lantheus Holdings. The transaction is expected to close early in the second quarter of 2020, subject to approval by Lantheus Holdings and Progenics stockholders, regulatory approvals, and certain other customary closing conditions.

EXHIBIT INDEX

Exhibit Number *	Description
2.1 (1)	Agreement and Plan of Merger, dated as of October 1, 2019, among Lantheus Holdings, Inc., Plato Merger Sub, Inc. and Progenics Pharmaceuticals, Inc.
2.2 (2)	Amended and Restated Agreement and Plan of Merger, dated as of February 20, 2020, among Lantheus Holdings, Inc., Plato Merger Sub, Inc. and Progenics Pharmaceuticals, Inc.
3.1(3)	Amended and Restated Certificate of Incorporation of the Registrant.
3.1(4)	Amended and Restated By-laws of the Registrant.
4.1(5)	Specimen Certificate for Common Stock, \$0.0013 par value per share, of the Registrant.
4.2	Description of Capital Stock
10.1(6)	Progenics Pharmaceuticals, Inc. 2018 Performance Incentive Plan.
10.2(7)	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(8)	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.
10.4 (9)	Amendment to the Stock Purchase and Sale Agreement, dated May 9, 2019, by and between Progenics Pharmaceuticals, Inc., Molecular Insight Pharmaceuticals, Inc., and Highland Capital Management, L.P., as stockholders' representative.
10.5 (4)	Form of Non-Qualified Stock Option Award Agreement for Directors under the 2018 Performance Incentive Plan.
10.6 (4)	Form of Non-Qualified Stock Option Award Agreement for Employees under the 2018 Performance Incentive Plan.
10.6.3(10) ‡	Amended 2005 Stock Incentive Plan
10.6.5(11) ‡	Form of Restricted Stock Award Agreement
10.7(12) ‡	Form of Indemnification Agreement
10.25(13) †	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(14)	Membership Interest Purchase Agreement, dated April 20, 2006, between the Registrant and Cytogen Corporation.
10.27(14) †	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(15) †	Collaboration Agreement, effective June 14, 2005, by and between Seattle Genetics, Inc. and PSMA Development Company LLC.
10.37(16) †	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(16) †	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(17) †	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(17) †	License Agreement, dated September 1, 2012, by and between FUJIFILM RI Pharma Co., Ltd. and Molecular Insight Pharmaceuticals, Inc.
10.40(18) †	License Agreement, dated May 4, 2012, between Molecular Insight Pharmaceuticals, Inc., the University of Zurich and the Paul Scherrer Institute.
10.41(19)	License Agreement, dated December 15, 2000, between Molecular Insight Pharmaceuticals, Inc. and The Board of Governors of the University of Western Ontario.
10.43(20)	Controlled Equity OfferingSM Sales Agreement, dated October 12, 2018, by and between the Registrant and Cantor Fitzgerald & Co.
10.45(15) †	Collaboration Agreement, effective February 21, 2001, by and between Abgenix, Inc. and PSMA Development Company LLC.
10.46 (21) †	Lease, dated December 31, 2015, between the Registrant and WTC TOWER 1 LLC.
10.47(22) †	License Agreement, effective July 30, 2015 between the Registrant and The Johns Hopkins University.
10.48	Employment Offer Letter Agreement between the Registrant and Asha Das.
10.49(22)	Employment Offer Letter Agreement between the Registrant and Patrick Fabbio.
10.50	Employment Offer Letter Agreement between the Registrant and Benedict Osorio.
10.51	Employment Offer Letter Agreement between the Registrant and Bryce Tenbarge.
10.52(23)	License Agreement, dated April 28, 2016, between PSMA Development Company LLC and Bayer AS.

10.53(24)	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.
10.54	Consulting Services Agreement, dated November 15, 2019, between the Registrant and David Mims.
10.55	Form of Retention Bonus Agreement
10.56(25)	Consulting Services Agreement, dated as of March 4, 2020, by and between Progenics Pharmaceuticals, Inc. and Patrick Fabbio.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP.
31.1	Certification of David W. Mims, Interim 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 David W. Mims, 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

* 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 October 2, 2019.
- (2) Previously filed in Current Report on Form 8-K filed on February 20, 2020.
- (3) Previously filed in Current Report on Form 8-K filed on June 13, 2013.
- (4) Previously filed in Current Report on Form 8-K filed on November 15, 2019.
- (5) Previously filed in Registration Statement on Form S-1, Commission File No. 333-13627.
- (5) Previously filed in Current Report on Form 8-K filed on June 14, 2018.
- (7) Previously filed in Current Report on Form 8-K filed on May 31, 2018.
- (8) Previously filed in Current Report on Form 8-K filed on May 11, 2018.
- (9) Previously filed in Current Report on Form 8-K filed on May 14, 2019.
- (10) Previously filed in Current Report on Form 8-K filed on June 18, 2014.
- (11) Previously filed in Current Report on Form 8-K filed on July 8, 2008.
- (12) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
- (13) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2005.
- (14) Previously filed in Quarterly Report on Form 10-Q for the quarter ended June 30, 2006
- (15) Previously filed in Amendment No. 2 to Annual Report on Form 10-K/A for the year ended December 31, 2009.
- (16) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.
- (17) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.
- (18) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2013.
- (19) Previously filed in Registration Statement on Form S-1, Commission File No. 333-129570 filed by Molecular Insight Pharmaceuticals, Inc.
- (20) Previously filed in Registration Statement on Form S-3, Commission File No. 333-227805.
- (21) Previously filed in Current Report on Form 8-K filed on January 5, 2016.
- (22) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2015.
- (23) Previously filed in Current Report on Form 8-K filed on May 4, 2016.
- (24) Previously filed in Current Report on Form 8-K filed on November 7, 2016.
- (25) Previously filed in Current Report on Form 8-K filed on March 4, 2020.

† 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/ DAVID W. MIMS
David W. Mims
Interim Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 13, 2020

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.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ ANN L. MACDOUGALL</u> Ann L. MacDougall	Interim Chair	March 13, 2020
<u>/s/ DAVID W. MIMS</u> David W. Mims	Interim Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2020
<u>/s/ BRADLEY CAMPBELL</u> Bradley Campbell	Director	March 13, 2020
<u>/s/ KAREN J. FERRANTE</u> Karen J. Ferrante, M.D.	Director	March 13, 2020
<u>/s/ GÉRARD BER</u> Gérard Ber	Director	March 13, 2020
<u>/s/ HEINZ CHRISTOPH MÄUSLI</u> Heinz Christoph Mäusli	Director	March 13, 2020
<u>/s/ ERIC J. ENDE</u> Eric J. Ende	Director	March 13, 2020
<u>/s/ PATRICK FABBIO</u> Patrick Fabbio	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2020

DESCRIPTION OF CAPITAL STOCK

The following is a general summary of our common stock and preferred stock, certain provisions of our amended and restated certificate of incorporation (“certificate of incorporation”) and our amended and restated bylaws (“bylaws”), and applicable law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and our bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K for the year ended December 31, 2019.

Capital Stock

Our authorized capital stock consists of 160 million shares of common stock, par value \$0.0013 per share, and 20 million shares of preferred stock, par value \$0.001 per share. As of December 31, 2019, there were 86,560,817 shares of common stock outstanding, 200,000 shares held in treasury and 6,680,952 shares reserved for issuance upon exercise of stock options granted under Company incentive plans. No shares of preferred stock are issued and outstanding.

Common Stock. Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. As described in our proxy statement for each Annual Meeting of Stockholders, our bylaws require that in order to be elected in uncontested elections, a director nominee must receive a majority of the votes cast with respect to such nominee (the number of shares voted “for” a director nominee must exceed the number of votes cast “against” that nominee); directors are elected by a plurality vote (*i.e.*, candidates receiving the most votes are elected regardless of whether they constitute a majority) in contested elections. Holders of common stock are not entitled to cumulative voting rights with respect to the election of directors, and as a consequence, minority stockholders are not able to elect directors on the basis of their votes alone. Subject to preferences that may be applicable to any shares of preferred stock currently outstanding or issued in the future which could adversely affect common stockholders as described below, holders of common stock are entitled to receive ratably such dividends as may be declared by our board of directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of the Company, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then-outstanding preferred stock. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable. American Stock Transfer and Trust Company is the transfer agent and registrar for our common stock.

Preferred Stock. Our board of directors has the authority, without further vote or action by the stockholders, to designate and issue shares of preferred stock in one or more series and to designate the rights, preferences and privileges of each series, which may be greater than the rights of the common stock. We will fix in a certificate of designation the number of shares, the designation and the rights, preferences and privileges, including any dividend, conversion, voting or preemptive rights, terms of redemption, liquidation preferences and sinking fund terms, auction and remarketing procedures, and any transfer or other restrictions or limitations of or relating to any series of preferred stock. The Delaware General Corporation Law (“DGCL”) provides that in addition to any voting rights that may be provided in the applicable certificate of designation, preferred stockholders have the right to vote separately as a class on a proposed amendment to our charter involving certain fundamental changes in their rights. Preferred stock terms could adversely affect the voting power or other rights of common stockholders and the likelihood that they would receive dividend or liquidation payments, and could have the effect of delaying, deferring or preventing a change in control.

Certain Provisions of Our Charter and Bylaws and Delaware Law

Advance Notice Procedures for Director Nominations and Proposing Business

Our bylaws establish advance notice procedures for stockholders seeking to nominate directors at an annual or special meeting of stockholders, which require stockholders to provide written notice to our Corporate Secretary not less than 90 days and no more than 120 days prior to the first anniversary of the preceding year's annual meeting of stockholders. In order to comply with the advance notice requirements set forth in our bylaws, stockholders must be a holder of record and must comply with the other requirements of the advance notice requirements. Although our bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of directors to be elected at an annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed.

Proxy Access

Our bylaws also provide notice and informational requirements to an eligible stockholder or group of stockholders seeking to nominate a candidate for election to our board of directors and inclusion in the proxy materials that we distribute for our annual meeting of stockholders. The maximum number of nominees that may be nominated is up to the greater of two directors or 25 percent (rounded down to the nearest whole number) of the number of directors then serving on our board of directors.

Indemnification

Our bylaws provide that we will indemnify our directors and executive officers to the fullest extent permitted by Delaware law and that we may indemnify our other officers, employees and other agents. We may enter into indemnification contracts with our directors and officers and purchase insurance on behalf of any person whom we are required or permitted to indemnify. In addition, our charter provides that the liability of our directors for monetary damages shall be eliminated, except for (i) breach of the directors duty of loyalty to the Company or its stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) violating Section 174 of the DGCL, or (iv) any transaction from which the director derived an improper personal benefit. Pursuant to Delaware law and subject to the foregoing exceptions, our directors shall not be liable for monetary damages for breach of the directors' fiduciary duty of care to the Company and its stockholders. This provision does not eliminate the duty of care: in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief remain available under Delaware law, and it does not affect a director's responsibilities under any other law, such as U.S. federal securities laws or state or federal environmental or other laws.

Anti-Takeover Effects of Provisions of Delaware Law

We are subject to the provisions of Section 203 of the DGCL, which, subject to certain exceptions, prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the interested stockholder attained such status with the approval of the board of directors or the business combination is approved in a prescribed manner. A "business combination" includes a merger or asset sale involving or other transaction resulting in a financial benefit to the interested stockholder. Subject to various exceptions, an interested stockholder is a person who, together with affiliates and associates, owns, or within the past three years did own, 15% or more of a corporation's voting stock. This statute could prohibit or delay the accomplishment of mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire the Company.



Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Fax: (914) 789-2817
(914) 789-2800
www.progenics.com

November 6, 2018

[*]

Re: Offer of Employment

Dear Asha:

This letter is to confirm our offer to you for the position of Chief Medical Officer (CMO) reporting to Mark Baker – Chief Executive Officer (CEO) with Progenics Pharmaceuticals, Inc. This position includes the following compensation and benefits package:

Salary: \$18,750.00 semi-monthly (\$450,000.00 per year). Payday is the 15th and the last day of each month.

Equity Participation: You may be granted an option to purchase 125,000 shares of Progenics' Common Stock. This grant is subject to approval by the Compensation Committee of the Company's Board of Directors at its next meeting. The exercise price of the option will be the closing price per share of Progenics' Common Stock on the day the option is granted. The option will expire ten years from the date of grant and will be subject to the terms of the Company's Stock Incentive Plan. You will receive an option agreement setting forth the specific terms of your option grant.

Annual Bonus Plan: You will be eligible to participate in the Company Bonus Plan. Bonuses are based on Corporate and Individual Goal achievement. Your target bonus is 40%.

Sign-on bonus: You will be entitled to a sign-on bonus of \$25,000 to be paid within one month of your start date. The full amount of the sign-on bonus will be due back to the Company if you unilaterally terminate your employment within 180 days of your start date.

Relocation Reimbursement: You are eligible to receive up to \$25,000.00 of reimbursement for moving expenses. Moving expenses will be defined in accordance to the IRS standards. To qualify for the reimbursement you must relocate within the first 6 months of employment with Progenics. For further information regarding relocation reimbursement please contact Ria Barrett – Associate Director, Human Resources.

Benefits: Participation in Progenics' Medical, Dental, Vision, 401(k), and other benefit plans that are available for all professional employees. The Company currently matches 50% of employee's 401(k) contributions between 1% and 10% of compensation.

You will accrue 20 days of Paid Time Off (PTO) per year, prorated your first year from your start date.

Tuition Reimbursement: Reimbursement for tuition for all pre-approved course work at accredited institutions as described in the Company's Employee Resource Guide.



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Performance & Salary Reviews: Your performance will be assessed under our normal performance management cycle. You will receive a performance and salary review at the end of each calendar year beginning 2020.

Immigration Law: The Immigration Reform and Control Act of 1986 (IRCA) requires that Progenics, like all employers, verify the employment authorization of every employee hired in order to determine if the individual is legally authorized to work in the United States. The verification process requires that all new employees complete and sign an Employment Eligibility Verification Form (Form I-9) certifying United States citizenship or authorization to work in the United States. It also requires that employers examine specific documents that the employee must provide within two days of starting work or within twenty days if proof is presented that request has been made to the appropriate agency for the necessary documents.

As we have explained, the above offer is contingent on your successful completion of full background verification and the signing of the enclosed statements of basic information about which all new employees ought to be aware. This offer does not constitute a contract of employment. Please confirm your acceptance of this offer by signing and dating this letter and returning it to the Associate Director, Human Resources, Ria Barrett marked Personal & Confidential. I look forward to your joining Progenics on or before January 7th, 2019.

Very truly yours,

/s/ Mark Baker

Mark R. Baker
Chief Executive Officer
Progenics Pharmaceuticals, Inc.

I confirm my acceptance of employment with Progenics Pharmaceuticals, Inc. subject to the terms and conditions of employment as set forth herein.

/s/ Asha Das
Asha Das

November 7, 2018
Date



Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Fax: (914) 789-2817
(914) 789-2800
www.progenics.com

January 19, 2018

[*]

Re: Offer of Employment

Dear Ben:

This letter is to confirm our offer to you for the position of Senior Vice President, Quality reporting to Mark Baker, CEO with Progenics Pharmaceuticals, Inc. This position includes the following compensation and benefits package:

Salary: \$14,791.67 semi-monthly (\$355,000 per year). Payday is the 15th and the last day of each month.

Equity Participation: You may be granted an option to purchase 100,000 shares of Progenics' Common Stock. This grant is subject to approval by the Compensation Committee of the Company's Board of Directors at its next meeting. The exercise price of the option will be the closing price per share of Progenics' Common Stock on the day the option is granted. The option will expire ten years from the date of grant and will be subject to the terms of the Company's Stock Incentive Plan. You will receive an option agreement setting forth the specific terms of your option grant.

Annual Bonus Plan: You will be eligible to participate in the Company Bonus Plan. Bonuses are based on Corporate and Individual Goal achievement. Your target bonus is 35%.

Sign-on bonus: You will be entitled to a sign-on bonus of \$80,000 to be paid within one month of your start date. The full amount of the sign-on bonus will be due back to the Company if you unilaterally terminate your employment within one year of your start date.

Start date: approximately three weeks from clearance of full background verification.

Benefits: Participation in Progenics' Medical, Dental, Vision, 401(k), and other benefit plans that are available for all professional employees. The Company currently matches 50% of employee's 401(k) contributions between 1% and 10% of compensation.

You will accrue 20 days of Paid Time Off (PTO) per year, prorated your first year from your start date.

Tuition Reimbursement: Reimbursement for tuition for all pre-approved course work at accredited institutions as described in the Company's Employee Resource Guide.

Performance & Salary Reviews: Your performance will be assessed under our normal performance management cycle. You will receive a performance and salary review at the end of each calendar year beginning 2018.



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777 Old Saw Mill River Road
Tarrytown, New York 10591
Fax: (914) 789-2817
(914) 789-2800
www.progenics.com

Immigration Law: The Immigration Reform and Control Act of 1986 (IRCA) requires that Progenics, like all employers, verify the employment authorization of every employee hired in order to determine if the individual is legally authorized to work in the United States. The verification process requires that all new employees complete and sign an Employment Eligibility Verification Form (Form I-9) certifying United States citizenship or authorization to work in the United States. It also requires that employers examine specific documents that the employee must provide within two days of starting work or within twenty days if proof is presented that request has been made to the appropriate agency for the necessary documents.

As we have explained, the above offer is contingent on your successful completion of full background verification and the signing of the enclosed statements of basic information about which all new employees ought to be aware. This offer does not constitute a contract of employment. Please confirm your acceptance of this offer by signing and dating this letter and returning it to the Associate Director, Human Resources, Ria Barrett marked Personal & Confidential.

Very truly yours,

/s/ Mark Baker

Mark R. Baker
Chief Executive Officer
Progenics Pharmaceuticals, Inc.

I confirm my acceptance of employment with Progenics Pharmaceuticals, Inc. subject to the terms and conditions of employment as set forth herein.

/s/ Benedict Osorio
Benedict Osorio

January 20, 2018
Date



Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Fax: (914) 789-2817
(914) 789-2800
www.progenics.com

August 2, 2016

[*]

Re: Offer of Employment

Dear Bryce:

This letter is to confirm our offer to you for the position of Vice President, Commercial reporting to Mark Baker, Chief Executive Officer. This position includes the following compensation and benefits package:

Salary: \$13,541.67 semi-monthly (\$325,000 per year). Payday is the 15th and the last day of each month.

Equity Participation: You may be granted an option to purchase 75,000 shares of Progenics' Common Stock. This grant is subject to approval by the Compensation Committee of the Company's Board of Directors at its next meeting. The exercise price of the option will be the closing price per share of Progenics' Common Stock on the day the option is granted. The option will expire ten years from the date of grant and will be subject to the terms of the Company's Stock Incentive Plan. You will receive an option agreement setting forth the specific terms of your option grant.

Annual Bonus Plan: You will be eligible to participate in the Company Bonus Plan. Bonuses are based on Corporate and Individual Goal achievement. Your annual target bonus is 30%. You will be eligible for the bonus program for the fiscal year 2016, prorated at the equivalent of six-months of service.

Benefits: Participation in Progenics' Medical, Dental, Vision, 401(k), and other benefit plans that are available for all professional employees. The Company currently matches 50% of employee's 401(k) contributions between 1% and 10% of compensation.

You will accrue 20 days of Paid Time Off (PTO) per year, prorated your first year from your start date.

Tuition Reimbursement: Reimbursement for tuition for all pre-approved course work at accredited institutions as described in the Company's Employee Resource Guide.

Performance & Salary Reviews: Your performance will be assessed under our normal performance management cycle. You will receive a performance and salary review at the end of each calendar year beginning 2016.

Immigration Law: The Immigration Reform and Control Act of 1986 (IRCA) requires that Progenics, like all employers, verify the employment authorization of every employee hired in order to determine if the individual is legally authorized to work in the United States. The verification process requires that all new employees complete and sign an Employment Eligibility Verification Form (Form I-9) certifying United States citizenship or authorization to work in the United States. It also requires that employers examine specific documents that the employee must provide within two days of starting work or within twenty days if proof is presented that request has been made to the appropriate agency for the necessary documents.



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777 Old Saw Mill River Road
Tarrytown, New York 10591
Fax: (914) 789-2817
(914) 789-2800
www.progenics.com

As we have explained, the above offer is contingent on your successful completion of full background verification, verification of your previous income, and the signing of the enclosed statements of basic information about which all new employees ought to be aware. This offer does not constitute a contract of employment. Please confirm your acceptance of this offer by signing and dating this letter and returning it to the Senior Manager, Human Resources, marked Personal & Confidential. I look forward to your joining Progenics.

Very truly yours,

/s/ Mark Baker

Mark R. Baker
Chief Executive Officer
Progenics Pharmaceuticals, Inc.

I confirm my acceptance of employment with Progenics Pharmaceuticals, Inc. subject to the terms and conditions of employment as set forth herein.

/s/ Bryce Tenbarger
Bryce Tenbarger

August 3, 2016
Date



Progenics Pharmaceuticals, Inc.
 One World Trade Center
 47th Floor, Suite J
 New York, New York 10007
 (646) 975-2500
www.progenics.com

CONSULTING SERVICES AGREEMENT

PROGENICS CONTRACT NO. 000000

This Consulting Services Agreement ("**Agreement**") effective as of the November 15, 2019 ("**Effective Date**") is by and between **Progenics Pharmaceuticals, Inc.**, a corporation organized under the laws of the State of Delaware with a place of business at One World Trade Center, 47th Floor, Suite J, New York, New York 10007 ("**PROGENICS**") and **David W. Mims**, with a place of business at [*] ("**CONSULTANT**").

In consideration of the promises and mutual covenants contained herein and on the terms and conditions hereinafter set forth, it is agreed as follows:

1. SCOPE OF SERVICES

CONSULTANT is engaged by PROGENICS to provide interim Chief Executive Officer ("CEO") services (the "**Services**").

CONSULTANT will personally perform all Services hereunder. CONSULTANT shall be available to PROGENICS at its offices or such other places as the parties may agree, at such times as the parties may agree, and shall be available for telephone consultations as requested by PROGENICS. CONSULTANT shall perform all Services in a prompt and professional manner. CONSULTANT shall not be entitled to subcontract any of its obligations hereunder without PROGENICS' prior written approval. CONSULTANT will commute from his home in Alabama, and will work out of his home when he is not in the Progenics offices or at other locations on behalf of Progenics.

CONSULTANT's primary contact at PROGENICS with respect to the work performed hereunder will be PROGENICS' Board of Directors or such other individual(s) as PROGENICS may subsequently designate ("**PROGENICS Contact**").

CONSULTANT shall not remove any PROGENICS property from PROGENICS' premises without prior written authorization from PROGENICS; provided that CONSULTANT may have company property in his possession away from Progenics' premises for use in carrying out his duties under this agreement or as a board member.

2. COMPENSATION

CONSULTANT's fees for performance of Services ("**Monthly Retainer**") will be \$30,000 USD per month payable in arrears on the last business day of each month.

The parties estimate that Service fees hereunder will not exceed an aggregate dollar amount during the term of this Agreement of US \$225,000.00 ("**Maximum Service Fees**"). Any amount above the Maximum Service Fees must be approved in writing by PROGENICS.

In addition to the compensation set forth above, PROGENICS will reimburse CONSULTANT for reasonable out-of-pocket expenses actually incurred by CONSULTANT in the performance of the Services, including, but not limited to telephone and facsimile charges and calls, car rental, lodging, travel expenses, meals and associated expenses all in accordance with Progenics' current Travel Policy provided to CONSULTANT. CONSULTANT shall not be eligible to participate in any PROGENICS of 's employee benefit plans, fringe benefit programs, group insurance arrangements or similar programs.__

CONSULTANT shall submit invoices once a month to PROGENICS, which shall set forth the hours of Services performed by CONSULTANT (and brief description of such Services, if applicable) for the prior unbilled period, and the amount of out-of-pocket expenses incurred by CONSULTANT for which CONSULTANT seeks reimbursement. Such invoices shall be payable within thirty (30) days of receipt by PROGENICS. CONSULTANT shall provide PROGENICS with supporting receipts and documentation for any out-of-pocket expenses which individually exceed \$100.00 as an attachment to the billing statement. All invoices submitted by CONSULTANT shall reference the PROGENICS contract number on the first page of this Agreement. PROGENICS prefers invoices to be sent via email to AP@progenics.com. Alternatively, paper invoices may be mailed to PROGENICS at One World Trade Center, 47th Floor, Suite J, New York, New York 10007, Attn: Accounts Payable. PROGENICS does not accept invoices via facsimile.

CONSULTANT shall be required to devote CONSULTANT's full time and attention to the performance of the Services hereunder to PROGENICS; provided that CONSULTANT may continue to serve on other boards and undertake other investment and business activity consistent with his current activity.

3. TERM & TERMINATION

This Agreement shall enter into force and effect as of the Effective Date and shall remain in force and effect until June 30, 2020 unless terminated as set forth herein by either party.

This Agreement may be terminated by either party, which in the case of Progenics will be its Board of Directors, (i) for convenience upon fifteen (15) days written notice to the other, or (ii) upon default in performance of the other party, provided that the defaulting party shall be given not less than ten (10) days prior written notice of default and the opportunity to cure the default during such notice period. To the extent stated in the notice, CONSULTANT shall cease all Services as of the effective date of termination (the "Termination Date").

Promptly upon the expiration or termination of this Agreement, and earlier if requested by PROGENICS at any time, CONSULTANT shall deliver to PROGENICS (and shall not keep in CONSULTANT's possession or deliver to anyone else) all Confidential Information, as defined in Section 4 below, of PROGENICS (including all embodiments thereof) and all software, documentation, devices (including cell phones, computers and other electronics used by CONSULTANT), records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, equipment, other documents or property, or reproductions of any aforementioned items, or any other work product whatsoever, developed by CONSULTANT as part of or in connection with the Services or otherwise belonging to PROGENICS.

4. CONFIDENTIALITY

During the term of this Agreement, and for a period of three years following the expiration or termination of this Agreement, CONSULTANT shall keep confidential, and shall not use for any purpose other than in connection with the performance of CONSULTANT's obligations under this Agreement, any information, including without limitation, data, business plans, techniques, processes, trade secrets, or other technical or business information of PROGENICS that is directly or indirectly disclosed by or on behalf of PROGENICS to CONSULTANT, by any means, including written, oral, visual or electronic, or obtained or generated by CONSULTANT during or as a result of CONSULTANT's work for PROGENICS ("Confidential Information").

The foregoing obligations of confidentiality and nonuse shall not apply to any information that (i) is or becomes part of the public domain through no fault of CONSULTANT, (ii) was already known to CONSULTANT at the time of disclosure by PROGENICS, as evidenced by written records prepared prior to such disclosure, or (iii) is acquired by CONSULTANT from a third party having right to possess and disclose such information, provided that such third party did not receive such information directly or indirectly from PROGENICS. CONSULTANT shall use the same degree of care, but no less than a reasonable degree of care, to keep PROGENICS' Confidential Information confidential as CONSULTANT uses in safeguarding CONSULTANT's own confidential information.

In addition, CONSULTANT may disclose Confidential Information to the extent required to do so by regulatory or judicial authority to whose jurisdiction CONSULTANT is subject. CONSULTANT shall promptly notify PROGENICS of any such request so that PROGENICS may object to the request and/or seek an appropriate protective order.

CONSULTANT shall not disclose the existence or subject matter of this Agreement to any third party other than employees of PROGENICS with a need to know without prior written consent of PROGENICS.

5. OWNERSHIP OF MATERIALS

CONSULTANT shall promptly make full written disclosure to PROGENICS, shall hold in trust for the sole right and benefit of PROGENICS, and hereby assigns, transfers and conveys to PROGENICS, or its designee, all of CONSULTANT's worldwide right, title and interest in and to any and all inventions, original works of authorship, findings, conclusions, data, discoveries, developments, concepts, improvements, trade secrets, techniques, processes and know-how, whether or not patentable or registrable under patent, copyright or similar laws, that CONSULTANT may solely or jointly conceive, develop or reduce to practice, or cause to be conceived, developed or reduced to practice, in the performance of the Services or that result, to any extent, from use of PROGENICS' premises or property (collectively, the "**Inventions**"), including any and all moral rights and intellectual property rights inherent therein and appurtenant thereto, including, but not limited to, all patent rights, copyrights, trademarks, know-how and trade secrets and the rights to apply for the same (collectively, "**Intellectual Property Rights**"). CONSULTANT further acknowledges and agrees that all original works of authorship that are made by CONSULTANT (solely or jointly with others) in the performance of the Services (a "**Work**") and that are protectable by copyright are "works made for hire," as that term is defined in the United States Copyright Act. However, to the extent that any Work may not, by operation of any applicable law, be a work made for hire, CONSULTANT hereby assigns, transfers and conveys to PROGENICS all of CONSULTANT's worldwide right, title and interest in and to such Work, including all Intellectual Property Rights relating thereto. For avoidance of doubt, this Section does not apply to Consultants activity permitted by the proviso in the last paragraph of Section 2.

Upon the request and at the expense of PROGENICS, CONSULTANT shall execute and deliver any and all instruments and documents and take such other acts as may be necessary or desirable to document the assignment and transfer described herein or to enable PROGENICS to secure its rights in the Inventions, Works and Intellectual Property Rights relating thereto in any and all jurisdictions, or to apply for, prosecute and enforce Intellectual Property Rights in any and all jurisdictions with respect to any Inventions or Works, or to obtain any extension, validation, re-issue, continuance or renewal of any such Intellectual Property Right. Without limiting the foregoing, CONSULTANT shall disclose to PROGENICS all pertinent information and data with respect thereto and shall execute all applications, specifications, oaths and all other instruments which PROGENICS deems necessary in order to apply for and obtain such rights and in order to assign and convey to PROGENICS the sole and exclusive right, title and interest in and to such Inventions, Works and any Intellectual Property Rights relating thereto. If PROGENICS is unable for any other reason to secure CONSULTANT's signature to apply for or to pursue any application for any United States or foreign patent, trademark, copyright or other registration covering Inventions or Works assigned to PROGENICS hereunder, then CONSULTANT hereby irrevocably designates and appoints PROGENICS and its duly authorized officers and agents as CONSULTANT's agent and attorney in fact, to act for and in CONSULTANT's behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or trademark, copyright or other registrations thereon with the same legal force and effect as if executed by CONSULTANT.

CONSULTANT will only use any materials provided by or on behalf of PROGENICS consistent with and as contemplated by this Agreement and will not undertake any actions which would jeopardize the copyright, trademark, tradename and other intellectual property rights of PROGENICS or its affiliates in any such materials.

6. WARRANTIES

CONSULTANT hereby warrants and represents to PROGENICS that:

- A. the Services shall be performed strictly in accordance with this Agreement and applicable laws and in a competent, timely, professional and workmanlike manner using the standards of care, skill, and diligence normally provided by competent professionals in the performance of Services similar to that are contemplated by this Agreement;
- B. CONSULTANT has all rights, approvals, licenses, rights or other authorizations required to perform the Services, if any; and
- C. the Services and/or any portion thereof, shall not violate, infringe upon, or misappropriate any patent, copyright, trade secret, trade name, or other proprietary rights of any third party, or breach any contract by which CONSULTANT is bound, and that CONSULTANT has neither assigned nor otherwise entered into an agreement by which CONSULTANT purports to assign or transfer to a third party any right, title or interest in or to any technology or intellectual property right that would conflict with CONSULTANT's obligations under this Agreement (collectively, "**Infringement**").

7. INDEMNIFICATION

8. COMPLIANCE WITH LAWS

A. CONSULTANT shall comply with all requirements of any and all applicable federal, state, and local laws, rules and regulations relating to his performance of the Services hereunder.

B. CONSULTANT represents and warrants to PROGENICS that CONSULTANT is not and has never been (i) sanctioned by the Office of Inspector General of the Department of Health and Human Services, excluded from participating in any government health care program, or convicted of a criminal offense that could lead to CONSULTANT being sanctioned or excluded; (ii) debarred by the Food and Drug Administration under the Generic Drug Enforcement Act of 1992, 21 U.S.C. Section 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act, as amended, or any similar federal or state law or regulation, or (iii) other relevant professional licensing body. CONSULTANT shall immediately notify PROGENICS, during the term of this Agreement, upon becoming aware of any facts or circumstances reasonably expected to make such representations and warranties to become untrue. Upon receipt of such notice or if PROGENICS otherwise becomes aware of a threatened or actual sanction, exclusion, debarment, or disciplinary action, PROGENICS shall have the right to immediately terminate this Agreement for cause. PROGENICS reserves the right to screen CONSULTANT against the Office of Inspector General and General Services Administration exclusion databases, the U.S. Food and Drug Administration (“FDA”) debarment list, and any other relevant databases at any time during the term of this Agreement.

C. CONSULTANT hereby certifies that CONSULTANT has not and will not use in any capacity the services of any individual, corporation, partnership or association which has been debarred under 21 U.S.C. Section 306(a) or (b). In the event that CONSULTANT becomes aware of the debarment or threatened debarment of any individual, corporation, partnership or association providing services to CONSULTANT which directly or indirectly relate to CONSULTANT’s activities under this Agreement, CONSULTANT shall notify PROGENICS immediately. CONSULTANT understands that PROGENICS shall have the right to terminate this Agreement immediately upon receipt of such notice pursuant to the provisions of Section 3 hereof.

D. CONSULTANT acknowledges that PROGENICS conducts its relationships with healthcare professionals, in compliance with applicable laws and regulations (including, without limitation, the U.S. Anti-Kickback Statute, 42, U.S.C. §1320a-7(b)), and the PhRMA Code. CONSULTANT, in the performance of Services on behalf of PROGENICS, shall conduct its relationships with healthcare professionals, if any, in accordance with all applicable laws and the PhRMA Code.

E. CONSULTANT acknowledges PROGENICS’ commitment to comply with all applicable local, state, and federal laws, rules, regulations, and agreements, including, without limitation, transparency principles. To that end, CONSULTANT acknowledges and agrees that payments made pursuant to this Agreement may be reported by PROGENICS to government entities as required by law, rule, regulation, or agreement. CONSULTANT acknowledges that PROGENICS may be required to publicly disclose payments to CONSULTANT, including the identity of the CONSULTANT, the nature of any services performed by the CONSULTANT pursuant to this Agreement, and the value and nature of any payments to the CONSULTANT.

9. INDEPENDENT CONTRACTOR

Execution of this Agreement in no way creates, nor shall this Agreement be interpreted or construed as creating, an employment relationship between PROGENICS and CONSULTANT and it is understood CONSULTANT will be acting as an independent contractor.

10. INSIDER TRADING

While providing the Services, CONSULTANT may gain access to certain material non-public information regarding PROGENICS. CONSULTANT understands that should CONSULTANT gain access to such material non-public information, CONSULTANT will, in compliance with U.S. securities laws, refrain from buying or selling PROGENICS securities, or disclosing such information to others.

11. NOTICES

Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (a) delivered by hand; (b) sent by registered or certified mail, postage prepaid, return receipt requested; or (c) delivered by overnight carrier with signature of recipient confirming receipt to the other party at the address listed above.

12. GOVERNING LAW

This Agreement shall be governed by the laws of the State of New York, without reference to its choice of law principles.

13. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

14. WAIVER

Waiver by either party or the failure by either party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with respect to any subsequent breach of any provision hereof.

15. ASSIGNMENT

This Agreement is personal to PROGENICS. CONSULTANT may not assign this Agreement without the prior written consent of PROGENICS. Any purported assignment made in violation of this provision shall be null, void and without legal effect.

16. ENTIRE AGREEMENT; AMENDMENTS

This Agreement supersedes any previous understandings or agreements, whether written or oral, between the parties regarding the Services. This Agreement may be amended only by a written document signed by both parties. No pre-printed terms of any subsequent purchase order or invoice will add to, modify, or supersede the terms of this Agreement.

17. SURVIVAL

Any provision of or obligation under this Agreement, which contemplates performance or observance subsequent to any termination or expiration of this Agreement, shall survive any such termination or expiration, and shall continue in full force and effect. In addition, all provisions of this Agreement shall survive the termination or expiration of this Agreement to the fullest extent necessary to give the parties the full benefit of the bargain expressed herein and of the intent contemplated hereunder.

IN WITNESS WHEREOF, the parties hereto, by their duly authorized representatives, have signed this Agreement as of the Effective Date.

PROGENICS PHARMACEUTICALS, INC.

DAVID W. MIMS

By: /s/ Patrick Fabbio

By: /s/ David W. Mims

Name: Patrick Fabbio

Name: David W. Mims

Title: EVP & CFO

Title: CEO

Date: 1/7/20

Date: 1/7/20



Progenics Pharmaceuticals, Inc.
One World Trade Center, 47th Floor
Suite J
New York, NY 10007
Phone: (646) 975-2500
Fax: (646) 707-3626
www.progenics.com

October 11, 2019

[NAME]

c/o Progenics Pharmaceuticals, Inc.
One World Trade Center, 47th Floor
New York, NY 10007

Re: **Retention Bonus Agreement**

Dear [FIRST NAME]:

As you may know, Progenics Pharmaceuticals, Inc. (the "Company") has recently entered into an agreement to be acquired by Lantheus Holdings, Inc. ("Parent," and such acquisition, the "Company Sale"). The Company is pleased to offer you a total retention bonus opportunity of \$[TOTAL BONUS AMOUNT] on the terms and conditions set forth in this letter agreement.

Your total retention bonus opportunity consists of two parts:

1. If you remain employed with the Company through the closing of the Company Sale (the "Closing"), the Closing occurs on or before July 1, 2020 (the "Expiration Date"), and you continue to perform your duties for the Company through the Closing, the Company will pay you a cash bonus of \$[50% OF BONUS AMOUNT], subject to applicable withholdings and deductions.
2. If the Closing occurs on or before the Expiration Date and you remain employed with the Company through the date that is six (6) months after the Closing, the Company will pay you a cash bonus of \$[50% OF BONUS AMOUNT], subject to applicable withholdings and deductions.

Notwithstanding the foregoing, if the Closing occurs on or before the Expiration Date and, during the six (6)-month period after the Closing, your employment with the Company is terminated either (i) by such entity without Cause (as defined below), (ii) by you for Good Reason (as defined below), or (iii) as a result of your death or disability, the Company will pay you the entire amount of your cash bonus provided above (to the extent not previously paid). If, however, you cease to be employed by the Company (or a successor or affiliate) prior to the date that is six (6) months after the Closing for any reason other than as described in the preceding sentence, or if the Closing does not occur on or before the Expiration Date, this letter agreement will terminate and you will not be entitled to any payment of the bonus (or the second portion of the bonus in the case of such a termination of employment after the Closing) hereunder. As used herein, the term "Company" shall include any successor or affiliate thereof.

If you become entitled to payment of a bonus as described above, the Company will pay your bonus on or as soon as practicable after (and in all events within ten (10) business days after) the date the bonus is earned (the Closing in the case of the first portion of the bonus opportunity described above and the date that is six (6) months after the Closing in the case of the second portion of the bonus opportunity described above); provided, however, that if your bonus becomes payable in connection with a termination of your employment during the six (6)-month period after the Closing by the Company without Cause, by you for Good Reason, or due to your death or disability as described in the preceding paragraph, the bonus will be paid on (or within ten (10) business days following) your termination of employment.

For purposes of this letter agreement, the term “Cause” means the occurrence of any of the following: (i) your willful and continued failure to substantially perform your duties to the Company; (ii) your conviction for, or plea of nolo contendere to, a felony or any crime involving moral turpitude; (iii) your engagement in any malfeasance, fraud or dishonesty of a substantial nature in connection with your position with the Company; or (iv) such other willful act by you that materially damages the reputation of the Company. However, no act or failure to act, on your part shall be considered “willful” unless done, or omitted to be done, by you not in good faith and without reasonable belief that your action or omission was in the best interest of the Company. Notwithstanding the foregoing, if you are a party to an employment or similar agreement with the Company or any subsidiary of the Company, the term “Cause” shall, as used in this letter agreement, have the same meaning set forth in such employment or similar agreement if and to the extent such term is defined therein.

For purposes of this letter agreement, the term “Good Reason” means the occurrence, without your consent, of any of the following events: (i) a material reduction in your rate of base salary or target annual cash opportunity; or (ii) Parent’s relocation of your principal place of employment to a location outside of a seventy-five (75)-mile radius of New York City (unless such new place of employment is closer to your personal residence than the prior place of employment); provided, however, that none of the events described in this sentence shall constitute Good Reason unless you first notify Parent in writing describing in reasonable detail the condition which constitutes Good Reason within thirty (30) days of its occurrence, Parent fails to cure such condition within thirty (30) days after the Parent’s receipt of such written notice, and you terminate your employment within sixty (60) days after the end of such thirty (30)-day cure period.

The Company will require any successor (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this letter in the same manner and to the same extent the Company would be required to perform if no such succession had taken place. This letter will be binding upon and inure to the benefit of the Company and any such successor to the Company and will inure to the benefit of and be enforceable by your successors. Nothing contained in this letter constitutes an employment or service commitment by the Company (or any of its subsidiaries or successors) or affects your status as an employee at will who is subject to termination without cause at any time. This letter contains all of the terms and conditions of your retention bonus opportunity and supersedes all prior understandings and agreements, written or oral, between you and the Company and any of its subsidiaries with respect thereto. This letter may be amended only by a written agreement between you and the Company that expressly refers to this letter. The validity, interpretation, construction and performance of this letter shall be governed by the laws of the State of New York without regard to the conflicts of laws principles thereof. It is intended that any amounts payable under this letter shall either be exempt from or comply with Section 409A of the U.S. Internal Revenue Code so as not to subject you to payment of any additional tax, penalty or interest imposed under Section 409A, and the provisions of this letter will be construed and interpreted in accordance with such intent.

We appreciate your hard work and look forward to this next exciting chapter in the Company’s history. Should you have any questions regarding this bonus opportunity, please feel free to call me.

Progenics Pharmaceuticals, Inc.

/s/ Patrick Fabbio
Patrick Fabbio
Chief Financial Officer

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.

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 No. 333-227805) of Progenics Pharmaceuticals, Inc.,
- (2) Registration Statement (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 13, 2020, with respect to the consolidated financial statements 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, 2019.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 13, 2020

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

I, David W. Mims, 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 13, 2020

/s/ David W. Mims

David W. Mims
 Interim Chief Executive Officer
 (Principal Executive Officer)

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 13, 2020

/s/ Patrick Fabbio

Patrick Fabbio

Chief Financial Officer

(Principal Financial and Accounting Officer)

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

The undersigned Interim 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, 2019 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.

Date: March 13, 2020

/s/ David W. Mims

David W. Mims
Interim Chief Executive Officer
(Principal Executive Officer)

**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, 2019 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.

Date: March 13, 2020

/s/ Patrick Fabbio

Patrick Fabbio

Chief Financial Officer

(Principal Financial and Accounting Officer)