PROGENICS PHARMACEUTICALS INC
Form 10-K
March 11, 2016

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

Commission File No. 000-23143

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant on June 30, 2015, based upon the closing price of the Common Stock on The NASDAQ Stock Market LLC on that date of $7.46 per share, was $245,713,772 (1).

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

As of March 7, 2016, a total of 69,946,317 shares of Common Stock, par value $.0013 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2016 Annual Meeting of Shareholders are hereby incorporated by reference into Part III of this Form 10-K where such portions are referenced.

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PART I

This document and other public statements we make may contain statements that do not relate strictly to historical fact, any of which may be forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements contained in this communication that refer to Progenics' estimated or anticipated future results or other non-historical facts are forward-looking statements that reflect Progenics' current perception of existing trends and information as of the date of this communication. Forward looking statements generally will be accompanied by words such as "anticipate," "believe," "plan," "could," "should," "estimate," "expect," "forecast," "outlook," "guidance," "intend," "may," "might," "will," "possible," "potential," "predict," "project," or other similar words, phrases or expressions. Such statements are predictions only, and are subject to risks and uncertainties that could cause actual events or results to differ materially. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. While it is not possible to identify or predict all such matters, these differences between forward-looking statements and our actual results, performance or achievement may result from, among other things, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products which appear to be promising in early trials will not demonstrate efficacy or safety in larger-scale trials; clinical trial data on our products and product candidates will be unfavorable; our products will not receive marketing approval from regulators or, if approved, do not gain sufficient market acceptance to justify development and commercialization costs; the sales of RELISTOR® and other products by our partners and the revenue and income generated for Progenics thereby may not meet expectations; competing products currently on the market or in development might reduce the commercial potential of our products; we, our collaborators or others might identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not originating from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, declining sales or other adverse events.

We are also subject to risks and uncertainties associated with the actions of our corporate, academic and other collaborators and government regulatory agencies, including risks from market forces and trends; potential product liability; intellectual property, litigation and other dispute resolution, environmental and other risks; the risk that we may not be able to obtain sufficient capital, recruit and retain employees, enter into favorable collaborations, acquisitions or transactions or other relationships or that existing or future relationships or transactions may not proceed as planned; the risk that current and pending patent protection for our products may be invalid, unenforceable or challenged, or fail to provide adequate market exclusivity, or that our rights to in-licensed intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.

Risks and uncertainties to which Progenics is subject also include general economic conditions, including interest and currency exchange-rate fluctuations and the availability of capital; changes in generally accepted accounting principles; the impact of legislation and regulatory compliance; the highly regulated nature of our business, including government cost-containment initiatives and restrictions on third-party payments for our products; trade buying patterns; the competitive climate of our industry; and other factors set forth in this document and other reports filed with the U.S. Securities and Exchange Commission ("SEC"). In particular, we cannot assure you that RELISTOR will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, that any of our other programs will result in a commercial product or that we will be able to successfully complete our integration of EXINI Diagnostics AB ("EXINI") and to develop and commercialize its products.

We do not have a policy of updating or revising forward-looking statements and, except as expressly required by law, Progenics disclaims 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.

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 an Internet website that contains reports, proxy and information statements and other information regarding issuers, including Progenics, which file electronically with the SEC. You may obtain documents that we file with the SEC at http://www.sec.gov, and read and copy them at the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549. You may obtain information on operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We also make available free of charge our annual, quarterly and current reports and proxy materials on http://www.progenics.com.

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

In this document, RELISTOR®, a registered trademark, refers to methylnaltrexone – the active ingredient of RELISTOR – as it has been and is being developed and commercialized by or in collaboration with Salix Pharmaceuticals, Inc., a subsidiary of Valeant Pharmaceuticals International, Inc. ("Valeant"). Subcutaneous RELISTOR has received regulatory marketing approval for specific indications, and references to RELISTOR do not imply that any other form or possible use of the drug has received approval. RELISTOR's approved U.S. label and full U.S. prescribing information is available at www.RELISTOR.com. Other approved labels for RELISTOR apply in ex-U.S. markets. AZEDRA® is a trademark of our Molecular Insight Pharmaceuticals, Inc. ("Molecular Insight") subsidiary.

Item 1. Business

Progenics Pharmaceuticals, Inc., a Delaware corporation incorporated in 1986, develops innovative medicines and other products for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA, 1095 and PSMA ADC), and imaging agents (1404 and PyL) intended to enable clinicians and patients to accurately visualize and manage their disease. In late 2015 Progenics acquired EXINI Diagnostics AB, in order to obtain know-how and expertise for the development of imaging analysis tools and solutions. As a result of that transaction, Progenics also acquired the EXINI Bone BSI bone scan index product. EXINI Bone BSI, which is approved for use in Europe, Japan and the U.S. (though not yet available in the U.S.), is an analytical tool enabling health care professionals to quantify the results of bone scan images.

PRODUCTS IN DEVELOPMENT

	Description	Status
AZEDRA®	Treatment of malignant and/or recurrent pheochromocytoma and paraganglioma	Completed enrollment in pivotal Phase 2b clinical trial under Special Protocol Assessment ("SPA")
1404	Technetium-99m labeled PSMA targeted SPECT/CT imaging agent for prostate cancer	Phase 3 pivotal trial initiated
1404 Index	Analytical tool for analysis and indexing of 1404 images for prostate cancer	In development
PyL	Fluorinated PSMA-targeted PET imaging agent for prostate cancer	Clinical proof-of-concept study completed by Johns Hopkins University; Phase 1 trial design in process
PyL Index	Analytical tool for analysis and indexing of PyL images for prostate cancer	In development
1095	Treatment of metastatic prostate cancer	Phase 1Trial design in process
PSMA ADC	Treatment of metastatic castration resistant prostate cancer	Phase 2 testing in chemotherapy-experienced and chemotherapy-naïve patients completed
EXINI Bone BSI	Analytical tool for analysis of Bone Scan Index from bone scintigraphy images	Currently sold in Europe and Japan; planning for U.S. commercialization in process

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PARTNERED PRODUCTS	Indication	Status
RELISTOR®-Subcutaneous injection	Treatment of opioid-induced constipation ("OIC") in advanced-illness patients receiving palliative care when laxative therapy has not been sufficient and treatment of OIC in patients with non-cancer pain	Sold in the U.S., E.U., Canada, Australia and elsewhere; licensed to Valeant
RELISTOR®-Oral Tablets	Treatment of OIC	Phase 3 testing completed; New Drug Application (NDA) submitted. FDA has assigned a Prescription Drug User Fee Act action date of April 19, 2016
PRO 140	HIV treatment	Phase 3 study ongoing

Our principal clinical-stage product candidates in oncology are:

- AZEDRA, a radiotherapeutic product candidate in development as a treatment for malignant and/or recurrent pheochromocytoma and paraganglioma, rare tumors found in the adrenal glands and outside of the adrenal glands, respectively. AZEDRA has been granted Breakthrough Therapy and Orphan Drug designations, as well as Fast Track status in the U.S. Under a SPA agreement with the U.S. Food and Drug Administration (FDA), a Phase 2 registrational study is being conducted in patients with malignant and/or recurrent pheochromocytoma and paraganglioma; there is currently no FDA-approved therapy for the treatment of these ultra-orphan diseases.

- 1404 (trofolastat), a technetium-99m labeled small molecule which binds PSMA and is used as an imaging agent to diagnose and detect localized prostate cancer as well as soft tissue and bone metastases. We have completed a global multi-centered Phase 2 study assessing the diagnostic accuracy of 1404 imaging in men with high-risk prostate cancer and recently initiated a multi-center, open-label Phase 3 trial to determine the sensitivity and specificity of 1404 to correctly identify whether or not patients have clinically significant prostate cancer (generally, Gleason score >3+4).

- PyL (also known as [18F]DCFPyL) is a clinical-stage, fluorinated PSMA-targeted Positron Emission Topography (PET) imaging agent for prostate cancer that was discovered and developed at the Center for Translational Molecular Imaging at the Johns Hopkins University School of Medicine. A proof-of-concept study published in the April 2015 issue of the Journal of Molecular Imaging and Biology showed that the uptake of PyL is high in sites of putative metastatic lesions and primary tumors, suggesting the potential for high sensitivity in detecting prostate cancer.

- 1095, a PSMA-targeted Iodine-131 labeled small radiopharmaceutical molecule that is designed to deliver a dose of radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. In collaboration with Memorial Sloan-Kettering Cancer Center, we plan to submit an Investigational New Drug ("IND") application in the U.S. and initiate a Phase 1 clinical study.

- PSMA ADC, a fully human monoclonal antibody-drug conjugate designed to deliver a chemotherapeutic agent to cancer. A Phase 2, multicenter clinical trial to assess the safety, tolerability and anti-tumor activity of PSMA ADC has been completed in both the chemotherapy refractory and chemotherapy naïve patients with metastatic castration-resistant prostate cancer ("mCRPC").

See Clinical Trial Activities, below, for additional information concerning these studies and those for RELISTOR.

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

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PARTNERED PRODUCTS

- RELISTOR, the first approved treatment for OIC that addresses its underlying mechanism, decreases the constipating side effects induced by opioid pain medications such as morphine and codeine without diminishing their ability to relieve pain. RELISTOR subcutaneous injection is approved for sale in the U.S., E.U., Canada, Australia and elsewhere in single-use vials and pre-filled syringes, which are designed to ease preparation and administration for patients and caregivers. Under our License Agreement Valeant is responsible for developing and commercializing RELISTOR, including completing clinical development necessary to support regulatory marketing approvals for potential new formulations of the drug (such as an oral formulation of methylnaltrexone, the active ingredient in RELISTOR). RELISTOR was originally approved in 2008 for OIC in patients with advanced illness and in September 2014, received approval from the FDA for the treatment of OIC in patients taking opioids for chronic non-cancer pain.

RELISTOR net sales (losses) and related royalty income (loss) during the years 2013-2015 are set forth below. 2015 RELISTOR net sales and royalty income reported by Valeant were $43.8 million and $6.6 million, respectively. Valeant reported sales deductions in excess of gross sales resulting in a royalty loss from net RELISTOR losses during the fourth quarter of 2014, leading us to recognize an accrued royalty loss liability owed to Valeant of $0.7 million. Our recognition of royalty income (loss) for financial reporting purposes is explained in Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) and our financial statements included elsewhere in this document. Royalties are based on net sales reported by our commercialization collaborators.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
	(in thousands)				
2015:					
Net Sales	$900	$11,900	$8,000	$ 23,000	$43,800
Royalty Income	140	1,773	1,208	3,452	6,573
2014:					
Net Sales (Losses)	$4,800	$9,100	$10,800	$ (4,400)	$20,300
Royalty Income (Loss)	723	1,353	1,617	(657)	3,036
2013:					
Net Sales	$7,700	$7,900	$4,800	$ 19,000	$39,400
Royalty Income	1,155	1,174	719	2,847	5,895

- PRO 140 is a fully humanized IgG4 monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter T-cells. PRO 140 blocks the predominant HIV subtype (R5) entry into T-cells by masking this required co-receptor, CCR5. PRO 140 has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. PRO 140 has been designated a "fast track" product candidate by the FDA. PRO 140 is currently partnered with CytoDyn which announced in October 2015 that it had begun dosing in a Phase 3 study.

Clinical Trial Activities

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

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Progenics' practice is and has been to announce commencement and results of all of its 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 and RELISTOR.

AZEDRA. In 2006, prior to its acquisition by Progenics, Molecular Insight commenced a Phase 1 study with AZEDRA in 11 patients with pheochromocytoma / paraganglioma and metastatic carcinoid tumors to assess the safety, radiation dosimetry, and distribution metabolism of a single imaging dose of this compound. Following completion of this study, two dose-finding studies were conducted to determine a maximum tolerated therapeutic dose, and to assess safety, dosimetry and preliminary efficacy of AZEDRA in 21 patients with pheochromocytoma / paraganglioma and 15 with high-risk neuroblastoma, respectively.

Molecular Insight subsequently commenced a Phase 2 study of AZEDRA under the 2009 FDA SPA regarding the design of this intended registrational Phase 2 trial to evaluate the efficacy and safety of the administration of two therapeutic doses of the compound in patients with metastatic and/or recurrent pheochromocytoma or paraganglioma. The primary efficacy endpoint of this U.S. study was to determine the clinical benefit of AZEDRA based on the proportion of study participants with a reduction of all antihypertensive medication by at least 50% for at least six months. Of the 41 patients who were dosed with a therapeutic dose by Molecular Insight prior to the trial suspension in late 2010 due to lack of funding, 13 patients had achieved the primary endpoint of the study. Of the 44 patients who have received any dose of AZEDRA, including an imaging dose, 45.5% of patients reported serious adverse events ("SAEs"), the most common of which were hematologic (11.4%) treatment-related events. Other commonly reported SAEs included constipation, dyspnea and myelodysplastic syndrome (each at 4.5%). One case of constipation (2.3%), one case of dyspnea (2.3%) and both cases of myelodysplastic syndrome (4.5%) were designated as treatment related.

After acquiring Molecular Insight, Progenics resumed the Phase 2 study in December 2014 with the goal of completing the study as specified under the SPA. In July 2015, the FDA designated AZEDRA as a Breakthrough Therapy for the treatment of patients with iobenguane-avid metastatic or recurrent pheochromocytoma and paraganglioma. In December 2015, we announced that we had completed enrollment in the Phase 2 registrational study. We expect to report top-line data between December 2016 and March 2017.

1404. Prior to being acquired by Progenics, Molecular Insight conducted four Phase 1 studies with 1404 to establish proof-of-concept and dosimetry, and to assess a simplified kit preparation as compared to multi-step preparation. It commenced a Phase 2 safety and efficacy study in 2012 to assess the diagnostic accuracy of the compound imaging in men with high-risk prostate cancer scheduled for radical prostatectomy (RP) and extended pelvic lymph node dissection compared to histopathology. The primary objective of this Phase 2 international multi-center, multi-reader, open-label trial was to assess clinical safety as well as the compound's ability to detect prostate cancer within the prostate gland. Patient enrollment has been completed with 105 participants dosed at 20 centers in the U.S. and Europe. In the Phase 2 trial, SPECT/CT imaging with 1404 showed 94% sensitivity in detecting and imaging cancer in the prostate gland of high-risk patients prior to prostatectomy. "Sensitivity" refers to the ability of 1404 to correctly detect and image prostate cancer. In addition, 1404 was more sensitive than MRI in detecting primary prostate cancer (94% vs. 86%) and was a good predictor of lymph node involvement at prostatectomy (area under the curve (AUC) of 0.77 (0.65-0.89% CI)). Uptake of 1404 in the lobes of the prostate gland showed a significant correlation with Gleason score ($p<0.0001$). An additional Phase 1 study in 14 patients to assess safety and diagnostic accuracy of 1404 whole body and pelvic SPECT/CT imaging and pelvic MRI in normal healthy men without current evidence of prostate cancer has been completed. Overall, there have to date been no treatment related adverse events (AEs) reported in these studies, other than one mild injection site reaction.

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In January 2016, we announced that a Phase 3 clinical trial for 1404 had been initiated and enrollment commenced. This Phase 3 clinical trial is expected to enroll approximately 450 patients with biopsy-proven low-grade prostate cancer who are candidates for active surveillance but have planned to undergo radical prostatectomy (RP). The multicenter, multi-reader, open-label study will evaluate the specificity and sensitivity of 1404 to identify clinically significant prostate cancer. Histopathology of the tumor tissue will be used as the truth standard. An interim analysis will be performed after approximately one-third of the patients have been treated and will include an analysis for futility and also evaluate the need for a sample size re-estimation.

PyL. In July 2015, Progenics and the Johns Hopkins University entered into an exclusive worldwide licensing agreement for [18F]DCFPyL ("PyL"), pursuant to which Progenics obtained exclusive, worldwide (excluding Australia and New Zealand) rights to develop and commercialize PyL in PET imaging applications. PyL is a clinical-stage fluorinated prostate specific membrane antigen ("PSMA")-targeted PET imaging agent for prostate cancer. PyL, when used in conjunction with high-resolution PET imaging, has shown potential for use in identifying prostate cancer.

Preclinical and clinical studies of PyL have been conducted by investigators in the U.S. and Europe, including the Johns Hopkins University. Preclinical in vitro and in vivo studies have demonstrated that PyL binds to PSMA with high affinity and uptake of PyL is specific to prostate tumor tissues. A First-in-human study conducted at the Johns Hopkins University using this tracer in patients with prostate cancer has shown that PET imaging with PyL is feasible and generally well tolerated, with a dose of radiation typical for diagnostic radiotracers for PET. In that study, physiologic accumulation of PyL corresponded to the distribution of PSMA-expressing organs and excretion. Accumulation in primary tumor and metastatic lesions was very high which may permit the prospective detection of residual tumor following definitive local therapy (surgery or radiation) as well as regional or distant metastases with high sensitivity and specificity. Progenics plans to initiate a Phase 2 study in 2016 to assess the safety and efficacy of PyL in the detection of prostate cancer.

1095. There have been no clinical studies conducted to assess the safety and efficacy of 1095 in prostate cancer patients. However, clinical experience using 1095 in patients with mCRPC has been published by the University Hospital Heidelberg, Germany. Under a compassionate-use protocol at this German hospital, 28 patients with late stage, hormone- and chemotherapy- refractory prostate cancer, were administered a single therapeutic dose of MIP-1095. Overall, the 1095 therapeutic treatments were reported to be well-tolerated. Myelosuppression was the primary and most significant side effect and was observed in most of the patients varying in degree from mild to moderate. The changes in hematological parameters were reported to be not related to the activity administered. In some patients, evidence of transient non-hematological side effects, such as slight to moderate xerostomia and mucositis, were noted. Preliminary efficacy was demonstrated by PSA reduction, a general observation of a reduction in bone pain and improved quality of life, and radiographic reductions in disease burden as evidenced by reduction in lesion size, extent and number of lesions as seen on the diagnostic scans. Based on these encouraging data, Progenics plans to initiate a Phase 1study, in collaboration with Memorial Sloan Kettering Cancer Center to evaluate the safety, tolerability, and efficacy of 1095 as a therapeutic agent for the treatment of mCRPC.

PSMA ADC. To date, one Phase 1 and one Phase 2 study of PSMA ADC have been completed. An investigator-initiated Phase 2 study has also been completed.

The Phase 2, open-label, multicenter study of PSMA ADC was designed to assess the anti-tumor activity and tolerability of PSMA ADC in two groups of patients with mCRPC. The chemotherapy-experienced group (patients who had undergone chemotherapy with an agent such as docetaxel or cabazitaxel prior to the study) was comprised of 84 patients. The chemotherapy-naïve group (patients who had not previously undergone chemotherapy) was comprised of 35 patients. Both groups were required to have received and progressed on antiandrogen treatments such as abiraterone acetate and/or enzalutamide prior to the study (once these agents were commercially available for use).

In this Phase 2 study, PSMA ADC at a dosage of 2.3 mg/kg was administered as an intravenous infusion once every three weeks for up to eight doses. Some patients in the chemotherapy-experienced group may also have received PSMA ADC at a dosage of 2.5 mg/kg if it was well tolerated. The anti-tumor effect of PSMA ADC was assessed by pharmacodynamic parameters that included serum PSA, CTCs, and tumor measurements of target and non-target lesions. Safety was monitored by physical examination, collection of AEs, laboratory testing, measurement of antibodies to PSMA ADC, electrocardiogram (ECG), and measurement of biomarkers.

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Results showed that radiologic response rates for patients with decreases in tumor size or stable disease was 74% in chemotherapy-naïve patients and 61% in chemotherapy-experienced patients. Decreases in serum PSA of ≥30% over the study were seen in 19% of chemotherapy-experienced patients and 29% of chemotherapy-naïve patients. Decreases of ≥50% occurred in 6% of chemotherapy-experienced patients and 21% of chemotherapy-naïve patients. CTC decreases of ≥30% over were seen in 81% of chemotherapy-experienced patients and 92% of chemotherapy-naïve patients. Responses of ≥50% occurred in 75% of chemotherapy-experienced patients and 85% of chemotherapy-naïve patients.

Overall survival was 91.7% in the chemotherapy-experienced group and 97.1% in the chemotherapy-naïve group. Adverse events (AEs) associated with PSMA ADC observed in this phase 2 study through March 2015 have been consistent with those observed in the phase 1 study noted below; the most common treatment-related grade 3 or higher AEs in this study have been fatigue (15.3% at 2.3 mg/kg and 20.6% at 2.5 mg/kg), neutropenia (grade 4: 11.8% at 2.3 mg/kg and 8.8% at 2.5 mg/kg), peripheral neuropathy (grade 3 or higher: 8.2% at 2.3 mg/kg and 5.9% at 2.5 mg/kg), decreased electrolytes (12.9% at 2.3 mg/kg and 20.6% at 2.5 mg/kg) and anemia (7.1% at 2.3 mg/kg and 8.8% at 2.5 mg/kg). Thirty-one patients reported serious adverse events (SAEs) which included pancreatitis, sepsis/septic shock, abdominal pain, anemia, asthenia, atrial fibrillation, bacteremia, bone pain, chronic obstructive pulmonary disease, clostridium difficile sepsis, constipation, deep vein thrombosis, dehydration, diabetic ketoacidosis, diarrhea, dyspnea, electrocardiogram QT prolonged, fall, fatigue, febrile neutropenia, gastrointestinal inflammation, hematuria, ileus, lobar pneumonia, metabolic acidosis, metabolic encephalopathy, muscular weakness, myalgia, myocardial infarction, nausea, non-cardiac chest pain, orthostatic hypotension, pleural effusion, pneumonia primary atypical, sinus tachycardia, supraventricular tachycardia, vertigo and vomiting. Also reported were treatment-related SAEs including increases in blood creatine phosphokinase, lactic acid, gamma-glutamyltransferase, International Normalized Ratio (INR), lipase and decreases in blood leukocytes, neutrophils, calcium, potassium, sodium and phosphate.

There were 2 cases of drug-related sepsis in the 2.5 mg/kg dosing group that were deemed at least possibly related to PSMA ADC. Both of these patients subsequently died. The first, a patient hospitalized ten days following his first dose of study drug (2.5 mg/kg) with febrile neutropenia and E. coli positive blood cultures, progressed despite treatment to septic shock and died; both the investigator and Progenics considered this patient's septic shock as probably related to PSMA ADC. The second patient developed a rash and fever and was hospitalized for neutropenic fever, where further assessment revealed Strep Viridans bacteria (suspected to be from a tunnel catheter) in blood. Approximately two weeks after receiving study drug (also 2.5 mg/kg), this patient was intubated due to hypoxia and respiratory failure, and died three days after being removed from a ventilator. The investigator considered sepsis as unlikely related, bacteremia as probably related, and febrile neutropenia as definitely related to PSMA ADC; Progenics assessed sepsis as probably related, bacteremia as unlikely related, and febrile neutropenia as definitely related to PSMA ADC.

There was an additional case of drug-related sepsis that was deemed related to PSMA ADC in a subject in the 2.3 mg/kg group. This patient later died due to progression of his prostate cancer, which was not related to PSMA ADC. This patient was hospitalized with febrile neutropenia and sepsis 13 days following his first dose of study drug. He was treated with antibiotics, filgrastim, normal saline and sequential compression devices. He was transferred 3 days later to hospice care for progression of prostate cancer and died 11 days later. The febrile neutropenia and sepsis were considered related to PSMA ADC by the investigator. The death due to disease progression was not considered related to PSMA ADC.

The initial 12-week clinical trial period of the phase 1 study had evaluated up to four intravenous doses of PSMA ADC administered at three-week intervals. Following completion of the four doses, patients were offered, at their physicians' discretion, the option to continue treatment with PSMA ADC for up to an additional 39 weeks. The anti-tumor effect of the compound as measured by changes in PSA levels and number of CTCs was observed in the study across doses ranging from 1.8 mg/kg to 2.8 mg/kg, and durable responses were seen in some of these heavily pre-treated patients. PSMA ADC was generally well tolerated in patients at doses up to and including 2.5 mg/kg. Dose

limiting toxicities, primarily neutropenia, were seen at 2.8 mg/kg. The most commonly reported AEs were anorexia and fatigue. Five patients experienced SAEs, two of which resulted in death. One patient dosed at 1.8 mg/kg died from multi-organ failure due to acute pancreatitis: while no data suggested this event was drug-related, a possible relationship could not be definitively ruled out. A second patient died 11 days after receiving study drug at 2.8 mg/kg: septic shock was cited as the cause of death. The investigator considered septic shock as probably related and febrile neutropenia as definitely related to PSMA ADC.

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RELISTOR. In 2011 Progenics and its licensee completed a Phase 3 U.S. trial to evaluate the efficacy and safety of oral methylnaltrexone for the treatment of opioid-induced constipation in patients with chronic, non-cancer pain. This 804-patient trial assessed a once-daily oral methylnaltrexone dose of 150, 300 or 450 mg compared to placebo for 12 weeks: patients received one daily dose during the first four weeks and dosing on an as needed basis for the remaining eight weeks. Both the 300 and 450 mg treatment arms demonstrated statistically significant results for the primary endpoint of percentage of doses resulting in any rescue-free bowel movements (RFBMs) per patient within four hours of administration over four weeks of dosing, when compared to the placebo treatment arm, with 27.4% for the 450 mg group ($p<0.0001$) and 24.6% for the 300 mg group (p-value=0.004). Efficacy was also seen in both the 300 and 450 mg treatment groups for other endpoints, including change in weekly RFBMs from baseline over the first four weeks and one assessing response (responder/non-responder) to study drug during weeks one to four, where "responder" was defined as having three or more RFBMs per week, with an increase of at least one RFBM per week over baseline, for at least three out of the first four weeks. Overall, efficacy of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in patients with chronic, non-cancer pain, and the overall observed safety profile seen in patients treated with oral methylnaltrexone was comparable to placebo. Valeant's NDA for oral methylnaltrexone in the U.S. has been accepted for review by the FDA. The FDA has assigned a Prescription Drug User Fee Act action date of April 19, 2016.

The Phase 3 trial was undertaken after review and analysis of results from clinical trials initiated by Progenics' former collaboration partner, Wyeth Pharmaceuticals, and Progenics utilizing formulations of oral methylnaltrexone in patients with chronic, non-cancer pain receiving opioid treatment.

In one of these trials of the oral formulation utilized in the Phase 3 trial described above, 48% of the 25 patients receiving methylnaltrexone tablets laxated within four hours of treatment. In this study, there were no drug related SAEs reported, and the most frequent AEs were nausea and headache (10.8% each); others were vomiting (4.6%), abdominal pain and muscle spasms (3.1% each). Based on the data from this study and other information regarding oral methylnaltrexone, Progenics concluded that the methylnaltrexone tablet was active and generally well tolerated and that its safety, pharmacokinetics and activity profiles were comparable to that of subcutaneous methylnaltrexone, and decided to commence the phase 3 trial described above.

EXINI Acquisition

On November 20, 2015 we concluded a public tender offer (the "Offer") conducted pursuant to Swedish law to acquire EXINI Diagnostics, AB, a leader in the development of advanced imaging analysis tools and solutions for medical decision support. Under the terms of the Offer, Progenics offered to pay a total aggregate purchase price for all of the equity of EXINI of approximately $7 million funded from cash on hand. The acquisition was approved by the board of directors of Progenics, and unanimously recommended by the board of directors of EXINI to its shareholders. As of the end of the offer acceptance period on that date, the Offer had been accepted by shareholders representing a total of 17,794,850 shares, corresponding to 96.81 percent of the total shares in EXINI. EXINI was delisted and ceased to be publicly traded effective as of the close of trading on December 4, 2015 and Progenics has commenced an administrative process in Sweden to acquire the remaining outstanding EXINI shares.

The acquisition of EXINI complements Progenics's strategy to support its imaging and therapeutic agents with sophisticated analytical tools and other technologies that help physicians and patients visualize, understand, target and treat cancer. EXINI has demonstrated experience in the successful development and commercialization of technology for medical image analysis and machine learning, which will provide Progenics with in-house development capabilities in these areas that it can apply to its own pipeline, including its prostate cancer imaging agents 1404 and PyL.

EXINI's primary product, EXINI Bone BSI, employs an artificial intelligence-based approach to apply techniques of statistical analysis and pattern recognition to quantify the information produced by bone scintigraphy (bone scan)

images used to view cancer present in the skeleton. EXINI Bone BSI uses the Bone Scan Index developed by Memorial Sloan Kettering Cancer Center to measure the extent of bone metastases. The Bone Scan Index is a standardized methodology for classifying "hotspots" appearing on bone scan images as possible metastases, and then computing bone tumor involvement by taking into account (i) the area of the metastasis, (ii) the area of the anatomical region on which the metastasis is located and (iii) a formula for the regional proportion of total skeletal mass in the affected area. When all such potential metastases viewed in the hotspots on the bone scan are added together, the resulting Bone Scan Index number reflects the apparent percentage of total skeletal mass taken up by the tumors. The EXINI Bone BSI tool "reads" bone scans and produces a standard, automated Bone Scan Index quantification.

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EXINI Bone BSI is currently approved for use in Japan, Europe and the United States (but not yet available for sale in the United States). To date, EXINI has engaged in only limited efforts to commercialize its EXINI Bone BSI analytical tool in Europe and has licensed it to FUJIFILM in Japan. Planning for commercialization in the U.S. is currently in process.

Research and Development Expenses

Research and development is essential to our business. During each of the years ended December 31, 2015, 2014 and 2013, we incurred research and development costs of $28.2 million, $28.6 million and $34.6 million, respectively. For additional information relating to our research and development expenses, see Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Research and Development Expenses.

License and Other Agreements

Following is a summary of certain agreements relating to our business.

Oncology

We acquired Molecular Insight in January 2013 by purchasing all of its outstanding capital stock for 4,452,593 shares of Progenics common stock in a private transaction. Under the agreement, we also agreed to pay to the former stockholders potential milestones, in cash or Progenics stock at our option, of up to $23 million contingent upon achieving specified commercialization events and up to $70 million contingent upon achieving specified sales targets relating to the acquired company's products and the timing of these payments, if any is highly uncertain. In addition to utilizing its own proprietary technology, Molecular Insight has 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 approximately $1.1 million. The agreement may be terminated by the licensors upon certain material defaults by, and automatically terminates upon certain bankruptcy events relating to Molecular Insight, and may be terminated by us on prior written notice.

- A 2012 out-license agreement with FUJIFILM RI Pharma Co., Ltd. for the development and commercialization of 1404 in Japan, with an upfront payment and the right to receive potential future milestone and royalty payments.

- A 2000 exclusive license agreement with The University of Western Ontario for worldwide sublicensable rights to certain intellectual property related to production methodologies relevant to AZEDRA. Under this 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 approximately $0.3 million. The agreement, which either party may terminate upon certain bankruptcy events or material defaults, continues through the last to expire of the related patent rights.

On August 4, 2015, we announced an exclusive worldwide licensing agreement for [18F]DCFPyL ("PyL"), a clinical-stage prostate specific membrane antigen (PSMA)-targeted imaging agent for prostate cancer, from Johns Hopkins University. PyL, when used in conjunction with high-resolution PET imaging, has shown potential for use in

identifying prostate cancer and sites of distant metastasis. Progenics intends to focus the development of PyL with high resolution PET imaging to detect and localize recurrent disease in patients who have experienced a biochemical relapse. 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 approximately $2.8 million.

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Our PSMA Development Company LLC subsidiary has a collaboration agreement with Seattle Genetics, Inc. ("SGI") under which SGI has granted us an exclusive worldwide license to its proprietary antibody-drug conjugate (ADC) technology. We have the right to use this technology, which is based in part on technology licensed by SGI from third parties, to link chemotherapeutic agents to our monoclonal antibodies that target prostate specific membrane antigen utilizing technology licensed to us, through Cytogen Corporation, from Sloan-Kettering Institute for Cancer Research. We are responsible for research, product development, manufacturing and commercialization of all products, and are obligated to make maintenance and milestone payments and to pay royalties to SGI and its licensors, as applicable, on a percentage of net sales. The SGI agreement terminates at the later of (i) the tenth anniversary of the first commercial sale of each licensed product in each country or (ii) the latest date of expiration of patents underlying the licensed products. We may terminate the agreement upon advance written notice; SGI may terminate if we fail to cure a breach of an SGI in-license after written notice; and either party may terminate after written notice upon an uncured breach or in the event of the other party's bankruptcy.

PSMA Development Company LLC also has a worldwide exclusive licensing agreement with Abgenix (now Amgen Fremont, Inc.) to use its XenoMouse® technology for generating fully human antibodies to PSMA. We are obligated to make development and commercialization milestone payments with respect to products incorporating an antibody generated utilizing that technology, along with royalties based upon net sales of such products. Abgenix may terminate this agreement for cause, after an opportunity to cure, upon 30 days' prior written notice; we have the right to terminate upon 30 days prior written notice. The agreement continues until the later of the expiration of specified patents or seven years from the first commercial sale of eligible products.

RELISTOR

Under our License Agreement, Valeant 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. Valeant 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 our Agreement with Valeant, we recognized in the third quarter of 2014 a $40 million development milestone for the chronic non-cancer pain indication approval, and remain eligible to receive (i) a development milestone of up to $50 million upon U.S. marketing approval of an oral formulation of RELISTOR, and (ii) up to $200 million of commercialization milestone payments upon achievement of specified U.S. sales targets, ranging from $10 million when calendar-year U.S. net sales first exceed $100 million, to $75 million when such sales first exceed $1 billion. We also receive royalties of 15% of calendar-year worldwide net sales by Valeant and its affiliates up to $100 million, and are eligible to receive (i) 17% on the next $400 million of such sales, and 19% on such sales over $500 million, and (ii) 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Valeant receives from sublicensees outside the U.S. In the event that marketing approval for the oral formulation is subject to a Black Box Warning or Risk Evaluation and Mitigation Strategy (REMS), payment of a substantial portion of specified milestone amounts would be deferred, and be subject to achievement of the first commercialization milestone. On September 8, 2015, the FDA accepted for review Valeant's New Drug Application for RELISTOR tablets for the treatment of OIC in adult patients with chronic non-cancer pain, and assigned a Prescription Drug User Fee Act (PDUFA) action date of April 19, 2016.

The License Agreement may be terminated by either party upon an uncured material breach or specified bankruptcy events. In addition, Valeant may terminate the 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 Risk Factors.

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We have licensed to Valeant our exclusive rights to develop and commercialize methylnaltrexone, the active ingredient of RELISTOR, which we in-licensed from the University of Chicago. Our agreement with Chicago 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. The Chicago agreement, as amended in connection with our RELISTOR collaborations, including substantially all of Progenics' payment obligations thereunder, expires by its terms upon the expiration of the last to expire of the patents licensed thereunder, the last-to-expire of which expires in 2017.

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

Owned and in-licensed properties relating to 1404 have expiration ranges of 2020 to 2030; we view as most significant the composition-of-matter patent on the compound, as well as technetium-99 labeled forms, which expire in 2029 and 2030 in the U.S.; 2029 in the rest of the world. Patent applications directed to methods of use are pending worldwide, which if issued would expire in 2034.

The PyL patent family was licensed from Johns Hopkins University. Patent protection for the compound, radiolabeled forms of the compound, as well as methods of use expire in 2030 in the U.S. Corresponding family members are pending or issued worldwide, all expiring in 2029.

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

The intellectual property directed to PSMA ADC comprises co-owned and in-licensed properties. Composition-of-matter patents have expirations of 2022 and 2023 in the U.S and a pending U.S. application which would expire in 2026, if issued. An allowed U.S. application directed to methods of use will expire in 2029. Corresponding foreign counterparts to the U.S. composition-of-matter patents in Europe and certain other markets will expire 2022 and 2026, along with a method of use patent which expires in 2029. We view all of these patents as significant.

With regard to our RELISTOR-related intellectual property, the composition-of-matter patent for the active ingredient of RELISTOR, methylnaltrexone, was invented in the 1970's and has expired. The University of Chicago, as well as Progenics and its collaborators, have extended the methylnaltrexone patent estate with additional patents and pending patent applications covering various inventions relating to the product. Valeant has listed in the FDA Orange Book six U.S. patents relating to subcutaneous RELISTOR, which have expiration dates ranging from 2017 to 2030, and two patents (expiring in 2024 and 2027) with Health Canada. Issued U.S. patents provide protection for the oral methylnaltrexone product until 2031.

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 and drug candidates directed toward PSMA or related compounds as well as methylnaltrexone and other 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.

Government Regulation

Progenics and its product candidates are subject to comprehensive regulation by the U.S. 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 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.

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None of our product candidates other than RELISTOR has 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 study, parameters used to monitor safety and effectiveness criteria to be evaluated. Each clinical study 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.

A New Drug Application, or NDA, is an application to the FDA to market a new drug. A Biologic License Application, or 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 biologic 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 (sNDAs) are submitted to obtain regulatory approval for additional indications for a previously approved drug, and are reviewed by the FDA in a similar manner.

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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 and Breakthrough Therapy Designations

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 United States. AZEDRA is designated as an Orphan Drug.

In the United States, 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 both fast track and breakthrough therapy 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.

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In 2012, as part of the Food and Drug Administration Safety and Improvement Act, a new regulatory scheme was established allowing expedited review of products designated as "breakthrough therapies." 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 the 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.

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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. In addition, Molecular Insight's 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

Under our License Agreement, Valeant is responsible for the manufacture and supply, at its expense, of all active pharmaceutical ingredient ("API") and finished and packaged products for its RELISTOR commercialization efforts, including contracting with contract manufacturing organizations ("CMOs") for supply of RELISTOR API and subcutaneous and oral finished drug product.

As to our other product candidates, the manufacture of biopharmaceuticals and radiopharmaceuticals is relatively complex and requires significant capital expenditures. As part of our ongoing efforts to manage our development costs and timely execute on our development plans, we rely on third parties for clinical manufacturing. We have engaged third-party CMOs to manufacture API and finished drug products for clinical trial supplies of AZEDRA, and are engaged in the process of putting in place sufficient manufacturing capacity to deliver commercial supplies in advance of the anticipated approval of AZEDRA. We have also partnered with third-parties to produce clinical trial supplies of 1404, PyL, 1095 and PSMA ADC, and may in the future undertake such efforts with respect to other assets and programs. As a result, we depend significantly on the availability of high quality CMO services. If we are unable to arrange for satisfactory CMO services, we would need to undertake such responsibilities on our own, resulting in our having to incur additional expenses and potentially delaying the development of our product candidates. See Risk Factors.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to participate in the commercialization of any of our drugs, we must develop these capabilities on our own or in collaboration with third parties. We may also choose to hire professional detailing and sales organizations or other third party sales personnel instead of developing our own staff. We intend to establish our own sales and marketing capabilities if and when we obtain regulatory approval of AZEDRA. In North America and Western Europe, patients in the markets for our drug candidates generally receive care from medical specialists in the areas of urology and oncology. We expect to utilize a specialized AZEDRA sales force in North America which can address a majority of key prescribers and support the successful commercialization of an Orphan Drug. We may also utilize a specialized sales force in North America for the sales and marketing of other drug candidates that we may successfully develop.

In circumstances or markets where a more favorable return may be realized, we may market products for which we obtain regulatory approvals through co-marketing, co-promotion, licensing or distribution arrangements with third-party collaborators. See Risk Factors.

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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. In September 2014, the FDA approved MOVANTIK™ (naloxegol), an oral peripheral mu-opioid receptor antagonist for patients with OIC developed by a Nektar Therapeutics-AstraZeneca PLC collaboration, which also has a related combination product in early stage development. MOVANTIK was made available to patients in 2015. In December 2014, AstraZeneca was granted a Marketing Authorization by the European Commission for MOVENTIG® (naloxegol) for the treatment of OIC in adult patients who have had an inadequate response to laxative(s). Cubist Pharmaceuticals, a subsidiary of Merck & Co., Inc., markets ENTEREG® (alvimopan) for the treatment of postoperative ileus, and has completed Phase 3 testing of a compound for OIC in chronic-pain patients. Sucampo Pharmaceuticals, Inc., in collaboration with Takeda Pharmaceutical Company Limited, markets AMITIZA® (lubiprostone), a selective chloride channel activator, for chronic idiopathic (non-opioid related) constipation, and in April 2013 received FDA approval of this drug for opioid-induced constipation. Shionogi & Co. has conducted Phase 3 testing for naldemedine, another mu-opioid receptor antagonist, for patients with OIC. Theravance, Inc. has completed Phase 2 clinical testing of an oral peripheral mu-opioid antagonist. In Europe, Mundipharma International Limited markets TARGIN® (oxycodone/naloxone), a combination of an opioid and a systemic opioid antagonist. Other prescription, as well as over-the-counter (OTC), constipation products are also prescribed first line for OIC.

As to our oncology pipeline, radiation and surgery are two traditional forms of treatment for prostate cancer. If the disease spreads, hormone (androgen) suppression therapy is often used to slow the cancer's progression, but this form of treatment can eventually become ineffective. We are aware of several competitors who are developing or have received approval for alternative treatments for castration-resistant prostate cancer, some of which are directed against PSMA, including Johnson & Johnson subsidiary Janssen Biotech, Inc.'s ZYTIGA® (abiraterone acetate), approved in 2011 for use in combination with prednisone as a second-line (after chemotherapy with docetaxel) for metastatic castration-resistant prostate cancer treatment, and later for use with prednisone for metastatic castration-resistant disease before the use of chemotherapy; Medivation, Inc.'s XTANDI® (enzalutamide), approved in August 2012 for patients with metastatic castration-resistant prostate cancer previously treated with docetaxel, and later for treatment of patients with metastatic castration-resistant prostate cancer before use of chemotherapy; and Bayer HealthCare Pharmaceuticals Inc.'s ALPHARADIN® (radium-223 dichloride) (marketed as XOFIGO®), approved in 2013 for treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. A competitive product to 1404 is PROSTASCINT®, which Aytu Bioscience Inc. acquired from Jazz Pharmaceuticals in 2015 and which is approved for detection of metastatic prostate cancer or relapsed or high-risk prostate cancer patients.

There are currently no approved anticancer treatments in the U.S. for malignant pheochromocytoma/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.

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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.

Human Resources

At December 31, 2015, we had 66 full-time employees, 11 of whom hold Ph.D. degrees and 2 of whom hold M.D. degrees. At that date, 44 employees were engaged in research and development, medical, regulatory affairs and manufacturing related activities and 22 were engaged in finance, legal, administration, sales and business development. We consider our relations with our employees to be good. None of our employees is covered by a collective bargaining agreement.

Item 1A. Risk Factors

Product Development-related Risks

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

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure increases for our product candidates that are based on new technologies, as well as technologies with which we have limited prior experience, such as those originally developed by Molecular Insight. Pre-clinical studies and clinical trials are long, expensive and highly uncertain processes that can take many years. It will take us, or our collaborators, several years to complete clinical trials and the time required for completing testing and obtaining approvals is uncertain. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or our and our partners' financial constraints. The FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical trials, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. Results attained in early human clinical trials may not be indicative of results in later clinical trials. In addition, many of our investigational or experimental drugs are at an early stage of development, and successful commercialization of early stage product candidates requires significant research, development, testing and approvals by regulators, and additional investment. Our products in the research or

pre-clinical development stage may not yield results that would permit or justify clinical testing. Our failure to demonstrate adequately the safety and efficacy of a product under development would delay or prevent marketing approval, which could adversely affect our operating results and credibility. The failure of one or more of our product candidates could have a material adverse effect on our business, financial condition and results of operations.

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

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

The long-term success of our acquisitions of Molecular Insight and EXINI will be subject to all of the risks and uncertainties described in these risk factors. In addition, the estimated fair values of Molecular Insight assets and liabilities reflected in our financial statements do not, given their uniqueness and attendant uncertainties, reflect actual transactions or quoted prices and may not correlate to any future values or results. Such information should not be interpreted or relied upon as indicative of any future value or results. Our failure to manage successfully any of our product candidates, technologies or programs could have an adverse impact on our business, and on the price of our stock.

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

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

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

would lead to delays in regulatory filings. If clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, such as the concerns expressed during consideration of the oral RELISTOR development program, we or our collaborators may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development programs for oral RELISTOR may be significantly delayed or terminated altogether.

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If the results of any future RELISTOR trials are not satisfactory or we or our collaborators encounter problems enrolling patients, clinical trial supply issues, setbacks in developing drug formulations, including raw material-supply, manufacturing, stability or other difficulties, or issues complying with protocols or applicable regulatory requirements, the entire development program for RELISTOR could be adversely affected in a material manner. Such scenarios could also befall our other clinical-stage product candidates. If any of our collaborators breach or terminate its agreement with us or otherwise fail to conduct successfully and in a timely manner the collaborative activities for which they are responsible, the preclinical or clinical development or commercialization of the affected product candidate or research program could be delayed or terminated. We generally do not control the amount and timing of resources that our collaborators devote to our programs or product candidates. We also do not know whether current or future collaboration partners, if any, might pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases or conditions targeted by our collaborative arrangements. Setbacks of these types could have a material adverse effect on our business, results of operations and financial condition.

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

We have limited experience in conducting clinical trials, and we rely on or obtain the assistance of others to design, conduct, supervise or monitor some or all aspects of some of our clinical trials, including our ongoing Phase 2 trial of PSMA ADC, Phase 3 trial of 1404 and the resumed AZEDRA Phase 2b trial. We have less control over the timing and other aspects of clinical trials for which we rely on third parties, such as CROs, clinical data management organizations, medical institutions or clinical investigators, than if we conducted them entirely on our own. These third parties may also have relationships with other entities, some of which may be our competitors. In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires us to comply with good clinical practices for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

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

Under our license agreement, Valeant generally has responsibility for conducting RELISTOR clinical trials, including all trials outside of the U.S. In addition, certain clinical trials for our product candidates may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. These arrangements expose us to the same considerations we face when contracting with third parties for our own trials.

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

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

RELISTOR-related Risks

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

We rely on Valeant to complete development and obtain regulatory approvals for RELISTOR worldwide. At present, our revenue is almost exclusively derived from royalty and milestone payments from our RELISTOR collaboration with Valeant, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue. We are and will be dependent upon Valeant and any other business partners with which we may collaborate in the future to perform and fund development, including clinical testing of RELISTOR, making related regulatory filings and manufacturing and marketing products, including for new indications and in new formulations, in their respective territories. Revenue from the sale of RELISTOR depends entirely upon the efforts of Valeant and its sublicensees, which have significant discretion in determining the efforts and resources they apply to sales of RELISTOR. Valeant may not be effective in obtaining approvals for new indications or formulations, marketing existing or future products or arranging for necessary sublicense or distribution relationships. Our business relationships with Valeant and other partners may not be scientifically, clinically or commercially successful. For example, Valeant has a variety of marketed products and its own corporate objectives, which may not be consistent with our best interests, and may change its strategic focus or pursue alternative technologies in a manner that results in reduced or delayed revenue to us. Valeant may also have commercial and financial interests that are not fully aligned with ours in a given territory or territories - which may make it more difficult for us to fully realize the value of RELISTOR, particularly in markets outside the U.S. We may have future

disagreements with Valeant, which has significantly greater financial and managerial resources which it could draw upon in the event of a dispute. Such disagreements could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as extensive financial and operational consequences to us and have a material adverse effect on our business, results of operations and financial condition. In addition, independent actions may be taken by Valeant concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property.

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Under our agreements with Valeant relating to RELISTOR, we rely on Valeant to, among other things, effectively commercialize the product and manage pricing, sales and marketing practices and inventory levels in the distribution channel. Assessing and reporting on these and other activities and metrics in connection with RELISTOR has become increasingly difficult as a result of financial reporting and internal control issues that have surfaced both at Valeant and its predecessor as our RELISTOR licensee, Salix. Our already limited visibility into the internal operations of Valeant and reliance on Valeant to accurately report information concerning the commercialization of RELISTOR has been further obscured by certain recent events at Valeant. On February 22, 2016 Valeant announced that it believed that approximately $58 million of net revenues previously recognized in the second half of 2014 should not have been recognized during that period, and that it expected to delay the filing of its Annual Report on Form 10-K. Valeant further announced that it continued to work with its independent advisors in its ongoing assessment of the impact on financial reporting and internal controls of the accounting issues it had discovered, including with respect to its relationship with Philidor Rx Services, LLC, a specialty pharmacy. Furthermore, prior to its acquisition by Valeant, Salix disclosed in January of 2015, in connection with an internal review of issues related to its management's prior characterizations of wholesaler inventory levels, that Salix's previously issued audited consolidated financial statements for the year ended December 31, 2013 and the first nine months of 2014, and the disclosures and related communications for each of those periods, required correction of certain errors and should no longer be relied upon. Valeant continues its efforts to assess and manage the potential ramifications relating to Salix's restatement of its historical financial results and Valeant's internal control over financial reporting.

The RELISTOR development program continues to be subject to risk.

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

Although the FDA has accepted for review Valeant's New Drug Application for RELISTOR tablets for the treatment of OIC in adult patients with chronic non-cancer pain and assigned a PDUFA action date of April 19, 2016, there can be no assurances that we and our partners will be able to successfully obtain approval to market oral RELISTOR in the U.S. or any other jurisdiction. In addition, our and our partners' ability to optimally commercialize either oral or subcutaneous RELISTOR in a given jurisdiction may be impacted by applicable labeling and other regulatory requirements. Valeant has previously disclosed in regulatory filings that additional information and additional guidance from the FDA could result in the termination of its oral RELISTOR development program. As noted in our risk factors on regulation and regulatory approvals, if clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, we or our collaborators may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development program for oral RELISTOR may in the future be significantly delayed or terminated altogether. In such an event, we could be faced with either further developing and commercializing the drug on our own or with one or more substitute collaborators, either of which paths would subject us to the development, commercialization, collaboration and/or financing risks discussed in these risk factors. Any such significant action adverse to development and commercialization of RELISTOR could have a material adverse impact on our business and on the price of our stock.

Certain RELISTOR-related patents are subject to generic challenge.

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

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

In addition to the above described ANDA notifications, in October 2015 Progenics also received notices of opposition to three European patents (EP 1615646, EP 2368554 and EP 2368553) relating to methylnaltrexone. The oppositions were filed separately by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH.

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

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

Operational and Regulatory Risks

We are subject to extensive regulation, which can be costly and time consuming, may not lead to marketing approval for our product candidates, and can subject us to unanticipated limitations, restrictions, delays and fines.

Our business, products and product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries, and include the recently enacted Sunshine Act under the Patient Protection and Affordable Care Act. These agencies and other entities regulate the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, recordkeeping, advertising, promotion and other aspects of our products and product candidates. We cannot guarantee that approvals of product candidates, processes or facilities will be granted on a timely basis, or at all. If we experience delays or failures in obtaining approvals, commercialization of our product candidates will be slowed or stopped.

Even if we obtain regulatory approval for a product candidate, the approval may include significant limitations on indicated uses for which the product could be marketed or other significant marketing restrictions, such as a REMS. For example, while subcutaneous RELISTOR is approved for OIC both in patients with advanced illness and for those with chronic, non-cancer pain, other formulations of and/or indications for RELISTOR may be subject to those or other such limitations and restrictions. Approvals for product candidates other than RELISTOR, if approved at all, may also be so limited or restricted.

If we or our collaborators violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we or they may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences. Under our license agreement with Valeant, we are dependent on Valeant for compliance with these regulatory requirements as they apply to RELISTOR. Valeant's subsidiary Salix disclosed that in February 2013 it received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding its sales and promotional practices for RELISTOR and certain of its other products, that it is continuing to respond to the subpoena and intends to cooperate fully with the subpoena and related government investigation, which has and will continue to increase its legal expenses and might require management time and attention, and that at the time of its disclosure it cannot predict or determine the timing or outcome of the

inquiry or its impact on Valeant's financial condition or results of operations.

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

Even if a product receives regulatory approval:

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

- Approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are relatively less financially advantageous to us than approval of greater or different scope or subject to an FDA-imposed REMS that imposes limits on the distribution or use of the product.

- Side effects (including different or aggravated effects such as SAEs encountered in our 1095 and PSMA ADC programs) identified after the product is on the market might hurt sales or result in mandatory safety labeling changes, additional pre-clinical testing or clinical trials, imposition of a REMS, product recalls or withdrawals from the market.

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

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

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

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

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

Valeant may not be able to fulfill manufacturing obligations for RELISTOR, a key raw material for which grows in Tasmania, either on their own or through third-party suppliers. A delay or disruption of supplies of RELISTOR would have a material adverse effect on the RELISTOR franchise, and therefore on our business as a whole. Our existing arrangements with suppliers for our other product candidates may result in the supply of insufficient quantities of our product candidates needed to accomplish our clinical development programs, and we may not have the right and in any event do not currently have the capability to manufacture these products if our suppliers are unable or unwilling to do so. We currently arrange for supplies of critical raw materials used in production of our product candidates from single sources. We do not have long-term contracts with any of these suppliers. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

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

We or our collaborators may engage third parties to manufacture our approved product and product candidates. We or our collaborators may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs. Under our license agreement with Valeant, Valeant is responsible for obtaining supplies of RELISTOR, including contracting with contract manufacturing organizations for supply of RELISTOR active pharmaceutical ingredient and subcutaneous and oral finished drug product. These arrangements may not be on terms that are advantageous and, as a result of our royalty and other interests in RELISTOR's commercial success, will subject us to risks that the counterparties may not perform optimally in terms of quality or reliability. In engaging third parties for these activities, we do not control many aspects of the manufacturing process, including compliance with current cGMP and other regulatory requirements. In order to commercialize our product candidates successfully, we or our collaborators need to be able to manufacture or arrange for the manufacture of products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. Manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up for large-scale production and subject to delays, inefficiencies and low yields of quality products. The cost of manufacturing some of our product candidates may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available on a timely basis or at all, our clinical trials could be seriously delayed, since these materials are time consuming to manufacture and cannot be readily obtained from third-party sources. We continue to be dependent on a limited number of highly specialized manufacturing and development partners, including single source manufacturers for certain of our product candidates. If we were to lose one or more of these key relationships, it could materially adversely affect our business. Establishing new manufacturing relationships, or creating our own manufacturing capability, would require significant time, capital and management effort, and the transfer of product-related technology and know-how from one manufacturer to another is an inherently complex and uncertain process.

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

Third-party manufacturers are required to comply with cGMP or similar regulatory requirements outside of the U.S. If manufacturers of our product or product candidates cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they may not be able to supply us with our product or product candidates. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays of several years in obtaining approval for a product candidate. We do not control the manufacturing operations and are completely dependent on

our third-party manufacturing partners or contractors for compliance with the applicable regulatory requirements for the manufacture of RELISTOR and our product candidates. Manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMP and similar regulatory requirements. Failure of any manufacturer of RELISTOR or any of our product candidates to comply with applicable cGMP or other regulatory requirements could result in sanctions being imposed on our collaborators or us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of RELISTOR or such product candidate and have a material adverse impact on our business, financial condition and results of operations.

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

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

It is generally difficult to determine the relative strength or scope of a biotechnology or pharmaceutical patent position in absolute terms at any given time. The issuance of a patent is not conclusive as to its validity or enforceability, which can be challenged in litigation or via administrative proceedings. The license agreements from which we derive or out-license intellectual property provide for various royalty, milestone and other payment, commercialization, sublicensing, patent prosecution and enforcement, insurance, indemnification and other obligations and rights, and are subject to certain reservations of rights. While we generally have the right to defend and enforce patents licensed to or by us, either in the first instance or if the licensor or licensee chooses not to do so, we must usually bear the cost of doing so. Under our license agreement with Valeant, Valeant generally has the first right to control the defense and enforcement of our RELISTOR patents. We may incur substantial costs in seeking to uphold the validity of patents or to prevent infringement. If the outcome of a dispute or contest is adverse to us, third parties may be able to use our patented invention without payment to us. Third parties may also avoid our patents through design innovation.

Patents have a limited life and expire by law.

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

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

Owned and in-licensed properties relating to the 1404 product candidate have expiration ranges of 2020 to 2030; we view as most significant the composition-of-matter patent on the compound, as well as technetium-99 labeled forms, which expires in 2029 and 2030 in the U.S.; 2029 in the rest of the world. Patent applications directed to methods of use are pending worldwide, which if issued would expire in 2034.

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

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

With respect to PSMA ADC, currently issued composition-of-matter patents comprising co-owned and in-licensed properties have expiration ranges of 2022 to 2023 in the U.S. and a pending U.S. application which would expire in 2026, if issued. An allowed U.S. application directed to methods of use will expire in 2029. Corresponding foreign counterparts to the U.S. composition-of-matter patents will expire 2022 and 2026, along with a method of use patent which expires in 2029. We view all of these patents as significant.

With regard to our RELISTOR-related intellectual property, the composition-of-matter patent for the active ingredient of RELISTOR, methylnaltrexone, was invented in the 1970's and has expired. The University, as well as Progenics and its collaborators, have extended the methylnaltrexone patent estate with additional patents and pending patent applications covering various inventions relating to the product. Valeant has listed in the FDA Orange Book six U.S. patents relating to subcutaneous RELISTOR, which have expiration dates ranging from 2017 to 2030, and two patents (expiring in 2024 and 2027) with Health Canada. Issued U.S. patents provide protection for the oral methylnaltrexone product until 2031.

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

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

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.

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Progenics and other businesses and organizations worldwide, and in particular technology-intensive activities such as biotechnology research and development, are increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to facilitate or perform basic research and development functions, business processes, internal and external communications, and other critical functions. Progenics relies on such systems for most aspects of its business. The size and complexity of computer, communications and other electronic networked data generation, storage and transfer systems make them potentially vulnerable to breakdown, malicious intrusion, computer viruses and data security breaches by unauthorized third parties, employees or others. Such events may permit unauthorized persons to access, misappropriate and/or destroy sensitive data and result in the impairment or disruption of important business processes, loss of trade secrets or other proprietary intellectual property or public exposure of personal information (including sensitive personal information) of employees, business partners, clinical trial patients, customers and others. Any of the foregoing could have a material adverse effect on our business, prospects, operating results and financial condition.

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

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

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

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

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

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

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

If we are unable to negotiate suitable collaboration agreements, our cash burn rate could increase and our rate of product development could decrease.

Our ability to generate revenue in the near term depends on the timing of achievement, if any, of certain payment triggering events under our existing collaboration agreements and our ability to enter into additional collaboration agreements with third parties. We may not be successful in negotiating additional collaboration arrangements with pharmaceutical and biotechnology companies to develop and commercialize product candidates and technologies. If we do not enter into new collaboration arrangements, we would have to devote more of our resources to clinical product development and product launch activities and to seeking additional sources of capital to fund those activities. If we were not successful in seeking such capital, our cash burn rate would increase or we would need to take steps to reduce our rate of product development. Our ability to enter into new collaborations may be dependent on many factors, such as the results of clinical trials, competitive factors and the fit of our programs with the risk tolerance of a potential collaborator, including in relation to regulatory issues, the patent portfolio, the clinical pipeline, the stage of the available data, overall corporate goals and financial position. If we are not able to generate revenue under our collaborations when and in accordance with our expectations or the expectations of industry analysts, this failure could harm our business and have an immediate adverse effect on the trading price of our common stock.

We lack sales and marketing infrastructure and related staff, which will require significant investment to establish and in the meantime may make us dependent on third parties for their expertise in this area.

We have no established sales, marketing or distribution infrastructure. If we receive marketing approval for a pharmaceutical product, significant investment, time and managerial resources would be required to build the commercial infrastructure required to market, sell and support it without a third-party partner. Should we choose to commercialize a product directly, we may not be successful in developing an effective commercial infrastructure or in achieving sufficient market acceptance. Alternatively, we may choose to market and sell products through distribution, co-marketing, co-promotion or licensing arrangements with third parties. We may also consider contracting with a third-party professional pharmaceutical detailing and sales organization to perform the marketing function for one or more products. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of product candidates, any revenues we receive will depend primarily on the efforts of third parties. We will not control the amount and timing of marketing resources these third parties devote to our products.

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 and note 10 in the notes to the consolidated financial statements in Item 15 of this Form 10-K.

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

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

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

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected. Under our license agreement with Valeant, we are responsible for product liability claims arising out of clinical trials that were conducted under our supervision. We are indemnified by Valeant under our license agreement with Valeant for product liability exposure arising from its supply, marketing and sales of RELISTOR, and maintain our own product liability insurance coverage in amounts and pursuant to terms and conditions customary for our industry, scale and the nature of our activities (subject to a deductible and an annual aggregate limitation), and other clinical trial or other insurance as required by contract and local laws. In October 2009, we released our former collaborator, Wyeth Pharmaceuticals, from its indemnification responsibility for product liability exposure arising from its marketing and sales of RELISTOR. Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all, and may not be available to us at a reasonable cost in the future. Our current insurance coverage and indemnification arrangements may not be adequate to cover claims brought against us, and are in any event subject to the insuring or indemnifying entity discharging its obligations to us.

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

Our research and development work and manufacturing processes involve the use of hazardous, controlled and radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure. We may be required to

incur significant costs to comply with environmental laws and regulations in the future.

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

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

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

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

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

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

restructuring of related operations. If physicians or other providers or entities involved with our products are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may adversely affect us.

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

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

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

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

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

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

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Competitive Risks

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

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

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

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

The extent to which any of our products achieves market acceptance will depend on competitive factors. Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. We face competition from many for-profit companies and major universities and research institutions in the U.S. and abroad. We face competition from companies marketing existing products or developing new products for diseases and conditions targeted by our technologies. We are aware of a number of products and product candidates, including those described in this Annual Report under Business – Competition, which compete or may potentially compete with RELISTOR, PSMA ADC or our other product candidates. For instance, there are product candidates in pre-clinical or clinical development that target the side effects of opioid pain therapy, and a marketed product for the treatment of post-operative ileus could compete with RELISTOR. We are aware of several competitors, including those described under Business – Competition, which have received approval for or are developing alternative treatments or diagnostics for castration-resistant prostate cancer, some of which are directed against PSMA. Any of these competing approved products or product candidates, or others which may be developed in the future, may achieve a significant competitive advantage relative to RELISTOR, PSMA ADC, 1404, AZEDRA, MIP-1095 or other product candidates.

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

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Financial Risks

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

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

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

We have a history of operating losses.

Progenics has incurred substantial losses throughout its history. A large portion of our revenue has historically consisted of upfront and milestone from licensing transactions. We have reported operating losses for 2015 and 2013 and while we reported operating income for 2014, as a result of a milestone payment from Valeant, the timing and amount of any similar transactions in the future is highly unpredictable and uncertain. Without upfront or other such payments, we operate at a loss, due in large part to the significant research and development expenditures required to identify and validate new product candidates and pursue our development efforts. Moreover, we have derived no significant revenue from product sales and have only in the last several years derived revenue from royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur net

operating losses and negative cash flow from operations in the future, which could increase significantly if we expand our clinical trial programs and other product development efforts. Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval for and then commercializing our product candidates, either alone or with others. We may not be able to develop and commercialize products beyond subcutaneous RELISTOR for OIC in patients with advanced illness and for those with chronic, non-cancer pain. Our operations may not be profitable even if any of our other product candidates under development are commercialized.

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

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

Progenics' stock price has a history of volatility and may be affected by selling pressure, including in the event of substantial sales of Progenics stock by former Molecular Insight stockholders. You should consider an investment in Progenics stock as risky and invest only if you can withstand a significant loss.

Our stock price has a history of significant volatility. It has varied between a high of $11.15 and a low of $4.86 in 2015 and between a high of $7.62 and a low of $3.10 in 2014. Factors that may have a significant impact on the market price of our common stock include the results of clinical trials and pre-clinical studies undertaken by us or others; delays, terminations or other changes in development programs; developments in marketing approval efforts; developments in collaborator or other business relationships, particularly regarding RELISTOR, PSMA ADC or other significant products or programs; technological innovation or product announcements by us, our collaborators or our competitors; patent or other proprietary rights developments; governmental regulation; changes in reimbursement policies or health care legislation; safety and efficacy concerns about products developed by us, our collaborators or our competitors; our ability to fund ongoing operations; fluctuations in our operating results; general market conditions; and the reporting of or commentary on such matters by the press and others. At times, our stock price has been volatile even in the absence of significant news or developments. The stock prices of biotechnology companies and securities markets generally have been subject to dramatic price swings in recent years, and financial and market conditions during that period have resulted in widespread pressures on securities of issuers throughout the world economy.

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

We expect to issue additional common stock in public offerings, private placements and/or through our January 2014 Sales Agreement with an investment bank, pursuant to which we may sell from time to time up to $50 million of our stock, and to issue options to purchase common stock for compensation purposes. We may issue preferred stock, restricted stock units or securities convertible into or exercisable or exchangeable for our common stock. All such issuances would dilute existing investors and could lower the price of our common stock. Sales of substantial numbers of outstanding shares of common stock, such as sales by former Molecular Insight stockholders of unregistered shares received in the acquisition, could also cause a decline in the market price of our stock. We require substantial external funding to finance our research and development programs and may seek such funding through the issuance and sale of our common stock, which we have done in follow-on primary offerings in late 2012, mid-2013 and February 2014. We have a shelf registration statement which may be used to issue up to approximately an additional $110 million of common stock and other securities before any underwriter discounts, commissions and offering expenses. We also have in place registration statements covering shares issuable pursuant to our equity compensation plans, and sales of our securities under them could cause the market price of our stock to decline. Sales by existing stockholders or holders of options or other rights may adversely affect the market price of our common stock.

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Other Risks

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

At 2015 year-end, our directors and executive officers together beneficially owned or controlled approximately 5 percent of our outstanding common shares, including shares currently issuable upon option exercises, and our five largest other stockholders approximately 52.8 percent. Should these parties choose to act alone or together, they could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could, among other things, have the effect of delaying or preventing a change in control of the Company, adversely affecting our stock price.

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, 2015.

Item 2. Properties

At December 31, 2015, we occupied approximately 72,900 square feet of laboratory and office space in Tarrytown, New York, pursuant to lease agreements expiring in December 2020 (subject to an early termination right) under which we pay rent and facilities charges including utilities, taxes and operating expenses.

On December 31, 2015, in connection with its decision to relocate its headquarters, the Company entered into a lease (the "Lease") for approximately 26,000 square feet of office space located in New York City. The Company intends to use the leased premises as its headquarters. The term of the Lease will commence on or about the earlier to occur of: (a) the later of (i) the parties entry into the Lease, (ii) the receipt of all necessary approvals or (iii) the date the landlord delivers possession of the built-out leased premises to the Company, or (b) the date the Company first occupies the leased premises. The Company expects the Lease term to commence in the second half of 2016. The Lease term expires on September 30, 2030, and we have an option to renew the term for an additional five years. The Lease contains customary default provisions that could result in the early termination of the Lease in the event the Company defaults under the terms and conditions of the Lease.

The Company's EXINI subsidiary leases approximately 4,000 square feet of office space in Lund, Sweden. The lease term expires on December 31, 2018, with an option to renew the term for an additional three years.

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Item 3. Legal Proceedings

Progenics is a party to a proceeding brought by a former employee on November 2, 2010 in the U.S. District Court for the Southern District of New York, complaining that Progenics had violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating the former employee. The former employee seeks reinstatement of his employment, compensatory damages and certain costs and fees associated with the litigation. In July 2013, the federal District Court hearing the case issued an order denying our motion for summary judgment dismissing the former employee's complaint. The case went to trial in July 2015 and on July 31, 2015 the jury awarded the former employee approximately $1.66 million in compensatory damages (held in escrow by the District Court as restricted cash and recorded in other current assets) primarily consisting of salary the former employee would have received during the period from his termination to the date of the verdict. We have accrued an amount in connection with this matter which we believe is probable and estimable. Certain ancillary matters in the case, including the former employee's claims for additional compensation, pre-judgment interest and the awarding of attorneys' fees, remain subject to dispute. Given that there are matters yet to be decided and an estimate of the additional exposure, if any, has yet to be determined there is a reasonable possibility that additional losses may be incurred. Progenics has moved for a new trial or, in the alternative, for remittitur and continues to assess the verdict and its options in the case, including a potential appeal.

In July 2015, Progenics was named as a defendant in a complaint brought by Lonza Sales AG ("Lonza") in the U.S. District Court for the District of Delaware arising from a multi-product license agreement entered into by Progenics and Lonza in April 2010. The complaint alleged that Progenics breached the multi-product license agreement and misappropriated trade secrets in connection with Progenics' sale of certain assets relating to the PRO 140 product to a third party, and sought unspecified damages and injunctive relief. On November 3, 2015, the District Court of Delaware denied Progenics' motion to dismiss the case. On November 17, 2015, Progenics answered Lonza's complaint and brought certain counterclaims against Lonza. On February 9, 2016, Progenics and Lonza agreed to settle and release their respective claims and to dismiss the litigation and, on February 19, 2016, the case was dismissed by the United States District Court for the District of Delaware. Other than the granting of the mutual releases, no consideration or damages were paid by either party to the other in connection with the settlement of the litigation.

On October 7, 2015 Progenics, Valeant and Wyeth LLC received notification of a Paragraph IV certification for certain patents for RELISTOR® (methylnaltrexone bromide) subcutaneous injection, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certification resulted from the filing by Mylan Pharmaceuticals, Inc. of an Abbreviated New Drug Application ("ANDA") with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

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

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

In addition to the above described ANDA notifications, in October 2015 Progenics received notices of opposition to three European patents relating to methylnaltrexone. The oppositions were filed separately by each of Actavis Group

PTC ehf. and Fresenius Kabi Deutschland GmbH.

Each of the above-described proceedings is in its early stages and Progenics and Valeant continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between Progenics and Valeant, Valeant has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement.

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Progenics and its affiliates 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 the Company, its results of operations, financial condition and cash flows.

Item 4. Not Applicable

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PART II

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

Price Range of Common Stock

Our common stock is quoted on The NASDAQ Stock Market LLC under the symbol PGNX. The following table sets forth, for the periods indicated, the high and low sales price per share of the common stock, as reported on NASDAQ.

		High	Low
2015:	Fourth quarter	$8.37	$5.20
	Third quarter	11.15	5.38
	Second quarter	9.27	4.86
	First quarter	7.84	5.35
2014:	Fourth quarter	$7.62	$4.26
	Third quarter	5.72	4.02
	Second quarter	4.65	3.10
	First quarter	7.45	3.75

On March 7, 2016, the last sale price for our common stock, as reported by The NASDAQ Stock Market LLC, was $4.90. There were approximately 69 holders of record of our common stock as of that date.

Comparative Stock Performance Graph

The graph below compares, for the past five years, the cumulative stockholder return on our common stock with the cumulative stockholder return of (i) the NASDAQ U.S. Benchmark (TR) Index and (ii) the ICB: 4577 Pharmaceuticals (Subsector) Index, assuming an investment in each of $100 on December 31, 2010.

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Dividends

Progenics has 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 financial data presented below as of December 31, 2015 and 2014 and for each of the three years in the period ended December 31, 2015 are derived from our audited financial statements, included elsewhere herein. The selected financial data presented below with respect to the balance sheet data as of December 31, 2013, 2012 and 2011 and for each of the two years in the period ended December 31, 2012 are derived from our audited financial statements not included herein. 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 Financial Statements and related Notes included elsewhere herein.

	Years Ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
Collaboration revenue	$1,955	$41,196	$1,595	$8,525	$76,764
Royalty income	6,608	3,101	5,923	4,963	3,046
Research grants	-	-	275	488	4,810
Other revenues	113	80	69	72	176
Total revenues	8,676	44,377	7,862	14,048	84,796
Expenses:					
Research and development	28,196	28,592	34,582	33,001	53,538
General and administrative	18,184	15,489	15,541	16,538	20,942
Intangible impairment charges	-	2,676	919	-	-
Change in contingent consideration liability	1,600	1,500	(200)	-	-
Total expenses	47,980	48,257	50,842	49,539	74,480
Other operating income	-	7,250	-	-	-
Operating (loss) income	(39,304)	3,370	(42,980)	(35,491)	10,316
Other income:					
Interest income	52	51	46	60	65
Total other income	52	51	46	60	65
(Loss) income before provision for income taxes	(39,252)	3,421	(42,934)	(35,431)	10,381
Income tax benefit	133	989	362	-	-
Net (loss) income	(39,119)	4,410	(42,572)	(35,431)	10,381
Net loss attributable to noncontrolling interests	(7)	-	-	-	-
Net (loss) income attributable to Progenics	$(39,112)	$4,410	$(42,572)	$(35,431)	$10,381
Per share amounts on net (loss) income attributable to Progenics:					
Basic	$(0.56)	$0.06	$(0.76)	$(1.02)	$0.31
Diluted	$(0.56)	$0.06	$(0.76)	$(1.02)	$0.31

	December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Consolidated Balance Sheet Data:					

Cash and cash equivalents	$74,103	$119,302	$65,860	$58,838	$70,105
Auction rate securities	-	-	2,208	3,240	3,332
Working capital	73,556	115,241	64,055	58,805	65,890
Total assets	131,251	161,037	114,541	76,308	80,110
Deferred revenue - current	-	-	-	838	204
Deferred revenue - long term	-	-	-	-	162
Other liabilities - long term	30,861	29,443	28,935	1,078	1,497
Total stockholders' equity	90,661	124,909	78,979	66,568	71,801

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A)

Overview

General. As discussed in Business, above, we develop innovative medicines and other products for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA, 1095 and PSMA ADC), and imaging agents (1404 and PyL) intended to enable clinicians and patients to accurately visualize and manage their disease. In addition, as part of its acquisition of EXINI Diagnostics AB in late 2015, Progenics acquired the EXINI Bone BSI bone scan index product, which is approved for use in Europe, Japan and the U.S. (though not yet available in the U.S.). EXINI Bone BSI is an analytical tool enabling health care professionals to quantify the results of bone scan images and planning for its commercialization in the U.S. is in process.

On November 12, 2015 we acquired 92.45% of EXINI through a public tender offer to the shareholders of EXINI in an all cash transaction. The acquisition was accounted for using the acquisition method of accounting, under which the acquired company's assets and liabilities were recorded at their estimated respective fair values as of the acquisition date in our consolidated financial statements. The difference between the estimated fair value of the acquisition consideration and fair value of the identifiable net assets represents potential future economic benefits arising from combining the companies, and has been recorded as goodwill. Through an extended acceptance period Progenics acquired an additional 4.36% of the outstanding shares of EXINI, and holds a total of 96.81% of such shares at December 31, 2015. The results of operations of the acquired company's business from November 12, 2015, the acquisition date, the estimated fair market values of the assets acquired and liabilities assumed, and goodwill are included in our consolidated financial statements since the date of the acquisition and are included in the discussion and analysis below. A portion of EXINI's results of operations from November 12, 2015 through December 31, 2015, has been allocated to the noncontrolling interests in EXINI.

Our 2013 acquisition of the privately-held Molecular Insight included the issuance of Progenics common stock in a private transaction not taxable to Progenics, and Progenics' agreement to pay potential milestones, in cash or Progenics stock at its option, of up to $23 million, contingent upon achieving specified commercialization events and up to $70 million contingent upon achieving specified sales targets relating to the acquired company's products. The acquisition was accounted for using the acquisition method of accounting, under which the acquired company's assets and liabilities were recorded at their estimated respective fair values as of the acquisition date in our consolidated financial statements. The difference between the estimated fair value of the acquisition consideration and fair value of the identifiable net assets represents potential future economic benefits arising from combining the companies, and has been recorded as goodwill. The results of operations of the acquired company's business from January 18, 2013, the closing date of the acquisition, the estimated fair market values of the assets acquired and liabilities assumed, and goodwill are included in our consolidated financial statements since the date of the acquisition and are included in the discussion and analysis below.

We have licensed RELISTOR to Valeant Pharmaceuticals, and have partnered other internally-developed or acquired compounds and technologies with third parties. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving proprietary research, development and clinical programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

Our current principal sources of revenue from operations are royalty, development and commercial milestones and sublicense revenue-sharing payments from Valeant's RELISTOR operations. Royalty and milestone payments from RELISTOR depend on success in development and commercialization, which is dependent on many factors, such as Valeant's efforts, decisions by the FDA and other regulatory bodies, competition from drugs for the same or similar indications, and the outcome of clinical and other testing of RELISTOR. In the fourth quarter of 2015, we received a

$1.5 million milestone payment as a result of CytoDyn dosing of the first patient in its Phase 3 clinical trial for PRO 140. In the third quarter of 2014, Progenics and Ono Pharmaceutical Co., Ltd. ("Ono"), its former licensee of RELISTOR in Japan, settled all claims between them relating to an arbitration commenced by Progenics in 2013, the parties' October 2008 License Agreement, and the former licensee's development and commercialization of the drug. In connection therewith, the parties exchanged mutual releases and the former licensee paid Progenics $7.25 million, which had been recorded as other operating income in 2014.

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We fund our operations to a significant extent from capital-raising. During 2013, we completed an underwritten public offering of 9.8 million shares of common stock at a public offering price of $4.40 per share, resulting in net proceeds of approximately $40.1 million, and in early 2014 sold an additional 8.75 million shares at $4.60 per share, for net proceeds of approximately $37.5 million.

Most of our expenditures are for research and development activities. During 2015, expenses for Oncology, primarily related to AZEDRA, 1404, PSMA ADC and 1095, were $26.8 million compared to $27.3 million in 2014 and $32.9 million in 2013. Expenses for RELISTOR and other programs in 2015 were $1.4 million, compared to $1.3 million in 2014 and $1.7 million in 2013. We expect to incur operating losses for the foreseeable future. At December 31, 2015, we held $74.1 million in cash and cash equivalents, a decrease of $45.2 million from $119.3 million at 2014 year-end. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year.

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

RELISTOR has been approved by regulatory authorities in the U.S., countries in the E.U., Canada, Australia and elsewhere since 2008 for treatment of OIC in advanced-illness patients receiving palliative care when laxative therapy has not been sufficient and in the U.S. since 2014 for the treatment of OIC in patients with non-cancer pain. Effective May 28, 2015, the European Commission approved RELISTOR Subcutaneous Injection for the treatment of OIC when response to laxative therapy has not been sufficient in adult patients, aged 18 years and older. The decision is applicable to all 28 European Union member states plus Iceland and Norway and granted RELISTOR an additional one year of marketing protection. Valeant is responsible for further developing and commercializing RELISTOR, including completing clinical development necessary to support regulatory marketing approvals for potential new indications and formulations of the drug, such as oral methylnaltrexone. Under our Agreement with Valeant, we received a development milestone of $40 million upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients in 2014 and are eligible to receive (i) a development milestone of up to $50 million upon U.S. marketing approval of an oral formulation of RELISTOR, (ii) up to $200 million of commercialization milestone payments upon achievement of specified U.S. sales targets, (iii) royalties ranging from 15 to 19 percent of net sales by Valeant and its affiliates, and (iv) 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Valeant receives from sublicensees outside the U.S. In the event marketing approval of the oral formulations of the drug is subject to a Black Box Warning or REMS, payment of a substantial portion of the milestone amount would be deferred, and subject to achievement of the first commercialization milestone (payable on annual U.S. sales first exceeding $100 million). On September 8, 2015, the FDA accepted for review Valeant's New Drug Application for RELISTOR tablets for the treatment of OIC in adult patients with chronic non-cancer pain, and assigned a PDUFA action date of April 19, 2016.

In January 2016, Valeant entered into a distribution agreement with Swedish Orphan Biovitrum AB (publ), also known as Sobi, for RELISTOR in Western Europe, Russia, Greece. Valeant has also licensed RELISTOR to Link Medical Products Pty Limited for distribution in Australia, New Zealand, South Africa and certain other markets in Asia, and also entered into an agreement with Lupin Limited for the distribution of RELISTOR in Canada.

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Results of Operations (amounts in thousands unless otherwise noted)

	2015	2014	2013	2015 vs. 2014 Percent Change	2014 vs. 2013
Revenues	$8,676	$44,377	$7,862	(80)%	464 %
Expenses	(47,980)	(48,257)	(50,842)	1 %	5 %
Other operating income	-	7,250	-	(100)%	100 %
Operating (loss) income	(39,304)	3,370	(42,980)	(1,266)%	108 %
Other income	52	51	46	2 %	11 %
Income tax benefit	133	989	362	(87)%	173 %
Net (loss) income	(39,119)	4,410	(42,572)	(987)%	110 %
Net loss attributable to noncontrolling interests	(7)	-	-	(100)%	N/A
Net (loss) income attributable to Progenics	$(39,112)	$4,410	$(42,572)	(987)%	110 %

Revenues (amounts in thousands unless otherwise noted):

Sources of revenue during the years indicated below were earned under license agreements with Valeant and other collaborators, and to a small extent research grants from the National Institutes of Health ("NIH") and sales of research reagents.

Sources of Revenue	2015	2014	2013	2015 vs. 2014 Percent Change	2014 vs. 2013
Collaboration revenue	$1,955	$41,196	$1,595	(95)%	2,483 %
Royalty income	6,608	3,101	5,923	113 %	(48)%
Research grants	-	-	275	N/A	(100)%
Other revenues	113	80	69	41 %	16 %
Total	$8,676	$44,377	$7,862	(80)%	464 %

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Collaboration revenue. During 2015, we recognized revenue from partnering arrangements, primarily resulting from a $1,500 milestone from CytoDyn as a result of dosing of the first patient in Phase 3 clinical trial of PRO 140, and reimbursement payments from other partnering arrangements.

During 2014, we recognized revenue from milestone partnering arrangements, primarily resulting from the $40,000 milestone from Valeant for the approval of subcutaneous RELISTOR for treatment of OIC in non-cancer pain patients and $157 in reimbursement payments, and a $1,000 milestone payment from FUJIFILM RI Pharma in the first quarter of 2014 and $37 in reimbursement payments.

During 2013, we recognized revenue from upfront and reimbursement payments from partnering arrangements consisting of (i) $676 from amortization of upfront payments for partnering the Company's PRO 140 and C. difficile programs, (ii) $420 from amortization of upfront payment and expense reimbursement for licensing 1404 in Japan, (iii) $295 from amortization of upfront payment and expense reimbursement for licensing RELISTOR, and (iv) a $189 upfront payment from another licensee.

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

	RELISTOR Net Sales		
	Years Ended December 31,		
	2015	2014	2013
U.S.	$40,700	$16,200	$35,000
Ex-U.S.	3,100	4,100	4,400
Global	$43,800	$20,300	$39,400

Valeant reported sales deductions in excess of gross sales resulting in royalty loss from net RELISTOR losses during the fourth quarter of 2014, leading us to recognize an accrued royalty loss liability owed to Valeant of $0.7 million.

Prior to its acquisition by Valeant, Salix made a series of disclosures concerning elevated inventory levels of certain of its products held by wholesale customers. We believe that Valeant continues to address inventory levels, and we are working diligently to improve our visibility into and better understand future sales and royalties.

Research grants. During the year ended December 31, 2013, we recognized $275 as revenue from federal government grants from the NIH to support research and development programs. We do not expect to recognize revenues from the NIH in the foreseeable future.

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

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Expenses (amounts in thousands unless otherwise noted):

Research and Development Expenses include salaries and benefit costs for personnel, clinical trial costs, supplies, product contract manufacturing costs for clinical trials, consulting expenses, license fees, royalty payments and other expenses. Research and development expenses decreased to $28,196 in 2015 from $28,592 in 2014 and from $34,582 in 2013. Portions of our expenses during 2013 were funded through grants from the NIH (see Revenues- Research Grants).

The changes in research and development expense, by category of expense, are as follows:

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013 Percent change
Salaries and benefits	$8,235	$9,003	$12,481	9%	28 %

2015 vs. 2014 Salaries and benefits decreased primarily due to a decline in average headcount.

2014 vs. 2013 Salaries and benefits decreased primarily due to a decline in average headcount, and reflecting approximately $1.5 million restructuring charges recorded in 2013.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013 Percent change
Share-based compensation	$1,099	$1,843	$2,012	40%	8 %

2015 vs. 2014 Share-based compensation decreased primarily due to cancellation of awards and a decrease in the number of options granted, partially offset by higher grant-date fair value of the options granted in 2015 compared to the prior year.

2014 vs. 2013 Share-based compensation decreased primarily due to lower stock expenses and the previous discontinuation of new restricted stock awards.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013 Percent change
Clinical trial costs	$5,859	$6,510	$8,862	10%	27 %

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2015 vs. 2014 Clinical trial costs decreased due to lower expenses for Oncology ($754), primarily related to PSMA ADC, resulting from completion of Phase 2 trial, partially offset by higher AZEDRA and 1404-related expenses.

2014 vs. 2013 Clinical trial costs decreased primarily due to lower expenses for Oncology ($2,337), primarily related to 1404 and PSMA ADC, partially offset by higher expenses for AZEDRA.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Laboratory and manufacturing supplies and equipment	$167	$193	$632	13%	69 %

2015 vs. 2014 Laboratory and manufacturing supplies and equipment decreased due to lower expenses in Oncology ($96), partially offset by higher expenses for other programs ($70).

2014 vs. 2013 Laboratory and manufacturing supplies and equipment decreased due to lower expenses for RELISTOR and other programs ($327) and Oncology ($112).

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Product contract manufacturing	$5,940	$5,191	$2,042	(14)%	(154)%

2015 vs. 2014 Contract manufacturing increased primarily due to higher expenses for Oncology ($747), resulting from higher AZEDRA-related expenses, partially offset by lower 1404-related expenses.

2014 vs. 2013 Contract manufacturing increased due to higher expenses for Oncology ($3,163), primarily related to AZEDRA, 1404 and PSMA ADC, partially offset by lower expenses for RELISTOR and other programs.

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

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Consultants	$1,477	$887	$905	(67)%	2 %

2015 vs. 2014 Consultants expense increased primarily due to higher expenses for Oncology ($454) and other programs ($136).

2014 vs. 2013 Consultants expense decreased primarily due to lower expenses for Oncology ($66), partially offset by higher expenses for RELISTOR and other programs ($48).

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

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
License fees	$388	$498	$567	22%	12 %

2015 vs. 2014 License fees decreased primarily due to lower expenses for RELISTOR ($150), partially offset by higher expenses for Oncology ($41).

2014 vs. 2013 License fees decreased primarily due to lower expenses for Oncology, partially offset by a license payment related to the $40,000 subcutaneous RELISTOR for non-cancer pain milestone.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Royalty expense	$688	$357	$624	(93)%	43 %

2015 vs. 2014 The increase in royalty expense was primarily due to higher net sales of RELISTOR in 2015.

2014 vs. 2013 The decrease in royalty expense was primarily due to lower net sales of RELISTOR in 2014.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Other operating expenses	$4,343	$4,110	$6,457	(6)%	36 %

2015 vs. 2014 Other operating expenses increased primarily due to higher facility related costs.

2014 vs. 2013 Other operating expenses decreased from 2013 primarily due to lower expenses for rent.

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General and Administrative Expenses increased to $18,184 in 2015 from $15,489 in 2014 and decreased slightly to $15,489 in 2014 from $15,541 in 2013, as follows:

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Salaries and benefits	$4,684	$4,398	$4,821	(7)%	9 %

2015 vs. 2014 Salaries and benefits increased primarily due to new executive positions in finance and human resources departments.

2014 vs. 2013 Salaries and benefits decreased primarily due to a decline in average headcount.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Share-based compensation	$1,849	$1,680	$1,534	(10)%	(10)%

2015 vs. 2014 Share-based compensation increased primarily due to higher grant-date fair value of options granted and an increase in the number of options granted, partially offset by higher cancellations of awards compared to the prior year.

2014 vs. 2013 Share-based compensation increased primarily due to higher stock option expenses.

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Consulting, legal and professional fees	$7,032	$5,060	$3,922	(39)%	(29)%

2015 vs. 2014 Consulting, legal and professional fees increased due to higher legal expenses ($1,145), primarily related to the action brought by a former employee, audit fees ($182), fees associated with the EXINI due diligence ($364), consulting ($295) and legal patent ($96) expenses partially offset by lower tax accounting ($89) and other fees ($21).

2014 vs. 2013 Consulting, legal and professional fees increased due to higher legal expenses ($1,873) and other fees ($93), partially offset by lower consulting ($539), legal patent ($227) and audit and compliance expenses ($62).

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	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Other operating expenses	$4,054	$3,806	$4,325	(7)%	12 %

2015 vs. 2014 Other operating expenses increased primarily due to higher expenses for travel ($81) and higher facility related pass-through cost ($73).

2014 vs. 2013 Other operating expenses decreased due to lower expenses for computer software ($120), recruiting ($102), rent ($58), taxes ($30), travel ($17) and other operating expenses ($192).

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Depreciation and amortization	$565	$545	$939	(4)%	42 %

2015 vs. 2014 Depreciation and amortization expense increased primarily due to amortization of finite-lived intangible assets resulting from the fourth quarter 2015 acquisition of EXINI, partially offset by a decrease due to lower asset balances for computers and machinery and equipment.

2014 vs. 2013 Depreciation and amortization expense decreased primarily due to lower machinery and equipment fixed asset balances.

Intangible Impairment Charges decreased in 2015 from 2014 and increased in 2014 from 2013, as follows:

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Intangible impairment charges (non-cash)	$ -	$2,676	$919	100%	(191)%

2015 vs. 2014 There were no intangible impairment charges recognized in 2015.

2014 vs. 2013 As of December 31, 2014 indefinite-lived intangible assets decreased by $2,679, from $31,379 to $28,700, of which a $2,660 impairment of the indefinite-lived ONALTA and MIP-1095 assets and a $16 impairment of the finite-lived ONALTA asset balance were incurred due to our review of these intangible assets, with the corresponding impairment charges recorded in the Consolidated Statements of Operations. As of December 31, 2013 indefinite-lived intangible assets decreased by $919, from $32,298 to $31,379, resulting from our annual impairment testing, with the corresponding expense recorded in the general and administrative expenses in the Consolidated Statements of Operations. This impairment was the result of change in the estimated timing of beginning cash inflows from 2014 to 2018 and an increase in discount rate from 15% to 18% for the ONALTA intangible asset.

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Change in Contingent Consideration Liability increased in 2015 from 2014 and in 2014 from 2013, as follows:

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Change in contingent consideration liability (non-cash)	$1,600	$1,500	$ (200)	(7)%	(850)%

2015 vs. 2014 The review of the contingent consideration liability fair value resulted in a $1,600 increase, from $17,200 to $18,800, resulting primarily from a decrease in the discount period, a 0.2% increase in the risk-free rate and a 5% increase in asset volatility. Changes in the contingent consideration liability are recorded as non-cash expense in the Consolidated Statements of Operations.

2014 vs. 2013 The review of the contingent consideration liability fair value resulted in a $1,500 increase, from $15,700 to $17,200, which has been recorded as non-cash expense in the Consolidated Statements of Operations. The increase in contingent consideration liability was primarily due to higher probability of success for 1404, partially offset by decrease due to lower projected revenues for MIP-1095.

Significant changes in estimates and assumptions underlying the estimated fair value of the contingent consideration liability would result in a significantly higher or lower fair value with a corresponding non-cash charge or credit to expenses.

Other operating income (amounts in thousands unless otherwise noted):

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Other operating income	$ -	$7,250	$ -	(100)%	100 %

2014 Other operating income consists of a third quarter 2014 payment received in connection with settlement of arbitration with our former licensee for RELISTOR in Japan.

Other income (amounts in thousands unless otherwise noted):

	2015	2014	2013	2015 vs. 2014 Percent change	2014 vs. 2013
Interest income	$ 52	$ 51	$ 46	2%	11 %

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2015 vs. 2014 Interest income increased due to slightly higher average balances in 2015 than in 2014.

2014 vs. 2013 Interest income increased primarily due to higher average balances in 2014 than in 2013, partially offset by decreases due to lower average interest rates in 2014 than in 2013.

Interest income, as reported, is primarily the result of investment income earned on money market funds.

Income Taxes (amounts in thousands unless otherwise noted):

For 2015, 2014 and 2013, income tax benefits of $133, $989 and $362, respectively, resulted from the change in the difference between carrying amounts of in-process research and development assets for financial reporting purposes and the amounts used for income tax purposes. For the year ended December 31, 2014, our book income was $4,410, resulting primarily from $40,000 in milestone revenue from Valeant and a $7,250 payment received in the settlement of arbitration with our former licensee for RELISTOR in Japan, however there was no provision for income taxes for 2014, due to taxable losses resulting primarily from the utilization of a portion of our deferred tax assets.

Net (Loss) Income (amounts in thousands unless otherwise noted):

Our 2015 net loss was $39,119 compared to 2014 net income of $4,410 and a net loss of $42,572 for 2013.

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

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

In 2015, we received a $1,500 milestone payment under our 2012 license agreement with CytoDyn Inc. for PRO 140, as a result of CytoDyn dosing the first patient in its Phase 3 clinical trial.

In 2014, prior to Salix's acquisition by Valeant, we received a $40,000 milestone payment from Salix, for the approval of subcutaneous RELISTOR for non-cancer pain patients, a $1,000 milestone payment from our Japanese partner in the 1404 program and a $7,250 payment upon settlement of arbitration with our former licensee for RELISTOR in Japan.

In 2013, we received a $5,000 upfront payment from partnering of the C. difficile program. We are eligible to receive future milestone and royalty payments. The 2013 receipt resulted in the reversal in 2013 of deferred tax assets and liabilities established in 2012 to reflect the net tax effects of temporary differences between the carrying amounts of certain assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

At December 31, 2015, we held $74,103 in cash and cash equivalents, a decrease of $45,199 from $119,302 at December 31, 2014. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. In addition, at December 31, 2013, our investment in auction rate securities classified as long-term assets on the Consolidated Balance Sheets amounted to $2,208, which was redeemed at par in the fourth quarter of 2014.

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If we do not realize sufficient royalty or other revenue from RELISTOR or other collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on certain programs, and/or take other economic measures.

Cash used in operating activities was $40,137 and $36,107 for 2015 and 2013, respectively, due to excess of expenditures on our research and development programs and general and administrative costs over cash received from collaborators. Cash provided by operating activities for 2014 was $13,726, due to the receipt of a $40,000 Salix milestone payment, partially offset by expenditures on our research and development programs and general and administrative costs. See Risk Factors.

During the first quarter of 2014, we established a $150 million replacement shelf registration statement which we used for our February 2014 underwritten public offering of 8.75 million shares of common stock at a public offering price of $4.60 per share, resulting in net proceeds of approximately $37,459. We may utilize this shelf registration for the issuance of up to approximately $110,000 of additional common stock and other securities, including up to $50,000 of our common stock under an agreement with an investment bank providing for at-the-market sales through the bank. In 2013, we completed an underwritten public offering under our 2011 shelf registration statement of 9.8 million shares of common stock at a public offering price of $4.40 per share (including the underwriters' overallotment option), resulting in net proceeds of approximately $40,078.

Sources of Cash (amounts in thousands unless otherwise noted)

Operating Activities. In addition to the $1,500 milestone payment mentioned above, during 2015 we received $3,592 under our collaborations, primarily consisting of $3,325 in royalties and reimbursements from Valeant, $203 in reimbursement payments relating to 1404, and $64 in royalties from our ONALTA out-license. In addition to the $7,250 settlement payment mentioned above, during 2014 we received $47,773 under our collaborations, consisting of (i) $40,000 milestone payment from Salix for the chronic non-cancer pain indication, (ii) $6,691 in royalties and reimbursements from Salix, (iii) $1,000 in milestone payment and $37 in reimbursement payments relating to 1404 and (iv) $45 from out-licenses of other assets. During 2013 we received $9,686 under our collaborations, consisting of (i) $5,125 in upfront and reimbursement payments from partnering of the C. difficile program, (ii) $3,952 in royalties and reimbursements from Salix, (iii) payments totaling $224 from out-licenses of other assets, and (iv) $385 in reimbursement payments relating to 1404.

We have in the past partially funded research programs through awards from the NIH, which we do not expect to receive in the foreseeable future. In 2013 we received $287 from all of our NIH awards.

Changes in Accounts receivable and Accounts payable for 2015, 2014 and 2013 resulted from the timing of receipts from Valeant, Fuji, other partnering transactions, and, principally in prior periods, NIH and Ono, and the timing of payments made to trade vendors in the normal course of business.

We have no committed external sources of funding or capital other than agreements under which collaborators and licensees have contractual obligations to make payments to us. Other than revenues from RELISTOR, we expect no significant product revenues in the immediate or near-term future, as it will take significant time to bring any of our current product candidates to the commercial marketing stage.

Investing Activities. During 2014 and 2013, net cash provided by investing activities included $2,400 and $1,100, respectively, in proceeds from redemption of auction rate securities. In addition, during 2015, 2014 and 2013, we received cash of $48, $143 and $174, respectively, from the sale of fixed assets.

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Financing Activities. During 2014 and 2013, net cash provided by financing activities included $37,459 and $40,078, respectively, in net proceeds from the issuance of common stock. In addition, during 2015, 2014 and 2013, we received cash of $1,737, $428 and $71, respectively, from exercise of stock options. The amount of cash we receive from these sources fluctuates commensurate with changes in the common stock price on and after the grant date.

Unless we obtain regulatory approval for additional product candidates and/or enter into agreements with corporate collaborators with respect to other proprietary assets, we will be required to fund our operations through sales of common stock or other securities or royalty or other financing agreements. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us may seriously jeopardize the future success of our business.

Uses of Cash (amounts in thousands unless otherwise noted)

Operating Activities. The majority of our cash has been used to advance our research and development programs, including conducting clinical trials, pursuing regulatory approvals for product candidates, filing and prosecuting patent applications and defending patent claims. For various reasons, including the early stage of certain of our programs, the timing and results of our clinical trials, our dependence in certain instances on third parties, many of which are outside of our control, we cannot estimate the total remaining costs to be incurred and timing to complete all our research and development programs.

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

Investing Activities. During 2015, we used cash of $6,202, net of cash acquired of $7, to acquire EXINI. During the past three years, we have spent $370, $714 and $137, respectively, on capital expenditures.

Financing Activities. During 2015, we used cash of $292 to purchase noncontrolling interests during the extended acceptance period following the acquisition date of EXINI.

Contractual Obligations

Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and fixed and contingent payments under licensing, collaboration and other agreements. The following table summarizes our contractual obligations as of December 31, 2015 for future payments under these agreements:

	Payments due by Period				
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
	(in millions)				
Operating leases	$40.2	$2.0	$7.7	$7.9	$22.6
License, collaboration and other agreements:					
Fixed payments	1.4	0.2	0.5	0.2	0.5
Contingent payments [1]	107.6	-	2.6	11.3	93.7
Total	$149.2	$2.2	$10.8	$19.4	$116.8

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(1)

Based on assumed achievement of milestones covered under each agreement, the timing and payment of which is highly uncertain.

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

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

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

Off-Balance Sheet Arrangements and Guarantees

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

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the U.S. Our significant accounting policies are disclosed in Note 2 to our financial statements included in this Report. The selection and application of these accounting principles and methods requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as certain financial statement disclosures. We evaluate these estimates on an ongoing basis. We base these estimates on historical experience and on various other assumptions that we believe reasonable under the circumstances. The results of these evaluations form the basis for making judgments about the carrying values of assets and liabilities that are not otherwise readily apparent. While we believe that the estimates and assumptions we use in preparing the financial statements are appropriate, they are subject to a number of factors and uncertainties regarding their ultimate outcome and, therefore, actual results could differ from these estimates.

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

Revenue Recognition. We recognize revenue from all sources based on the provisions of the SEC's Staff Accounting Bulletin (SAB) No. 104 (SAB 104) and ASC 605 Revenue Recognition.

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The FASB's ASC 605 Revenue Recognition specifies how to separate deliverables in multiple-deliverable arrangements, and how to measure and allocate arrangement consideration to one or more units of accounting, and provides that the delivered item(s) are separate units of accounting, if (i) the delivered item(s) have value to a collaborator on a stand-alone basis, and (ii), if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

Royalty revenue or loss is recognized based upon net sales of related licensed products, and is recognized in the period the sales (losses) occur, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement providing for the royalty. Royalty loss is recognized based upon reported sales deductions in excess of gross sales resulting in net losses and are recognized in the period net losses occur. Royalty loss is classified in royalty income in the consolidated statements of operations and the related accrued royalty loss liability is classified in accounts payable and accrued expenses in the consolidated balance sheets.

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

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

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

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

We apply a forfeiture rate to the number of unvested awards in each reporting period in order to estimate the number of awards that are expected to vest. Estimated forfeiture rates are based upon historical data on vesting behavior of employees. We adjust the total amount of compensation cost recognized for each award, in the period in which each award vests, to reflect the actual forfeitures related to that award. Changes in our estimated forfeiture rate will result in changes in the rate at which compensation cost for an award is recognized over its vesting period.

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

periods. Conversely, a lower volatility, shorter expected term and lower risk-free rate decreases such expense recognized in future periods as compared to prior periods.

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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.

Fair Value Measurements. During 2014, all of the $2,208 million (net of $192 million unrealized loss) auction rate securities remaining at December 31, 2013 were redeemed at par. Our available-for-sale investment portfolio consists of money market funds and is recorded at fair value in the accompanying Consolidated Balance Sheets in accordance with ASC 320 Investments – Debt and Equity Securities.

In–Process Research and Development, Intangible Assets-Technology and Goodwill. In connection with the acquisitions of Molecular Insight and EXINI, we have established 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 an intangible asset. An impairment test for indefinite-lived intangibles is performed annually in the fourth quarter, unless impairment indicators require an earlier evaluation. Finite-lived intangible assets are evaluated only when impairment indicators are present. IPR&D will be amortized upon and subject to commercialization of the underlying candidates and intangible assets-technology is amortized over the relevant estimated useful life.

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

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. The Company records 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 the Company records that amount as an accrual. If no amount within the range is a reasonable estimate, then the Company records 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 $62,855 million at December 31, 2015. As a result, we do not believe that these investment balances have a material exposure to interest-rate risk.

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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, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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, 2015.

On November 12, 2015, we became a majority owner of EXINI Diagnostics AB, which is included in our 2015 consolidated financial statements and constituted $1.1 million and $0.7 million of total and net assets, respectively, as of December 31, 2015 and $0.01 million and ($0.2) million of revenues and net (loss), respectively, for the year then ended. As the acquisition occurred during 2015, management excluded the EXINI business from its assessment of internal control over financial reporting.

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, 2015 as stated in their report which is provided below.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Progenics Pharmaceuticals, Inc.

We have audited Progenics Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2015, 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). Progenics Pharmaceuticals, Inc.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of EXINI Diagnostics AB, which is included in the 2015 consolidated financial statements of Progenics Pharmaceuticals, Inc. and constituted $1.1 million and $0.7 million of total and net assets, respectively, as of December 31, 2015 and $0.01 million and ($0.2) million of revenues and net (loss), respectively, for the year then ended. Our audit of internal control over financial reporting of Progenics Pharmaceuticals, Inc. also did not include an evaluation of the internal control over financial reporting of EXINI Diagnostics AB.

In our opinion, Progenics Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Progenics Pharmaceuticals, Inc. as of December 31, 2015 and 2014 and the related consolidated statements of operation, comprehensive (loss) income, stockholders' equity, and cash flows for

each of the three years in the period ended December 31, 2015 of Progenics Pharmaceuticals, Inc. and our report dated March 11, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut
March 11, 2016

Item 9B. Other Information

None.

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PART III

The information required by the Form 10-K Items listed in the following table will be included under the respective headings specified for such Items in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after December 31, 2015, which proxy statement is incorporated herein by reference:

Item of Form 10-K	Location in 2016 Proxy Statement
Item 10. Directors, Executive Officers and Corporate Governance	Election of Directors. Executive and Other Officers. Corporate Governance. Code of Business Ethics and Conduct.* Section 16(a) Beneficial Ownership Reporting and Compliance. *The full text of our Code of Business Ethics and Conduct is available on our website (www.progenics.com).
Item 11. Executive Compensation	Executive Compensation. Compensation Committee Report. Compensation Committee Interlocks and Insider Participation.
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	Equity Compensation Plan Information. Security Ownership of Certain Beneficial Owners and Management.
Item 13. Certain Relationships and Related Transactions, and Director Independence	Certain Relationships and Related Transactions. Affirmative Determinations Regarding Director Independence and Other Matters.
Item 14. Principal Accounting Fees and Services	Fees Billed for Services Rendered by our Independent Registered Public Accounting Firm. Pre-approval of Audit and Non-Audit Services by the Audit Committee.

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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, 2015 and 2014

Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts

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

(3) Item 601 Exhibits

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

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PROGENICS PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Progenics Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Progenics Pharmaceuticals, Inc. as of December 31, 2015 and 2014 and 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, 2015. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Progenics Pharmaceuticals, Inc. at December 31, 2015 and 2014 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Progenics Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2015, 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 11, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Hartford, Connecticut
March 11, 2016

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except for par value and share amounts)

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$74,103	$119,302
Accounts receivable, net	3,543	109
Other current assets	5,639	2,515
Total current assets	83,285	121,926
Fixed assets, net	2,407	2,552
Intangible assets, net	30,793	28,700
Goodwill	13,074	7,702
Other assets	1,692	157
Total assets	$131,251	$161,037
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$9,544	$6,570
Other current liabilities	185	115
Total current liabilities	9,729	6,685
Contingent consideration liability	18,800	17,200
Deferred tax liability	11,199	11,332
Other liabilities	862	911
Total liabilities	40,590	36,128
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $.001 par value; 20,000,000 shares authorized; issued and outstanding – none	-	-
Common stock, $.0013 par value; shares authorized - 160,000,000 in 2015 and 2014; issued - 70,146,317 in 2015 and 69,832,949 in 2014	91	91
Additional paid-in capital	594,511	589,826
Accumulated deficit	(501,379)	(462,267)
Accumulated other comprehensive loss	(26)	-
Treasury stock, at cost (200,000 shares in 2015 and 2014)	(2,741)	(2,741)
Total Progenics stockholders' equity	90,456	124,909
Noncontrolling interests	205	-
Total stockholders' equity	90,661	124,909
Total liabilities and stockholders' equity	$131,251	$161,037

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except net (loss) income per share)

	Years Ended December 31,		
	2015	2014	2013
Revenues:			
Collaboration revenue	$1,955	$41,196	$1,595
Royalty income	6,608	3,101	5,923
Research grants	-	-	275
Other revenues	113	80	69
Total revenues	8,676	44,377	7,862
Expenses:			
Research and development	28,196	28,592	34,582
General and administrative	18,184	15,489	15,541
Intangible impairment charges	-	2,676	919
Change in contingent consideration liability	1,600	1,500	(200)
Total expenses	47,980	48,257	50,842
Other operating income	-	7,250	-
Operating (loss) income	(39,304)	3,370	(42,980)
Other income:			
Interest income	52	51	46
Total other income	52	51	46
(Loss) income before income tax benefit	(39,252)	3,421	(42,934)
Income tax benefit	133	989	362
Net (loss) income	(39,119)	4,410	(42,572)
Net loss attributable to noncontrolling interests	(7)	-	-
Net (loss) income attributable to Progenics	$(39,112)	$4,410	$(42,572)
Net (loss) income per share attributable to Progenics - basic	$(0.56)	$0.06	$(0.76)
Weighted-average shares - basic	69,716	68,185	55,798
Net (loss) income per share attributable to Progenics - diluted	$(0.56)	$0.06	$(0.76)
Weighted-average shares - diluted	69,716	68,243	55,798

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(amounts in thousands)

	Years Ended December 31,		
	2015	2014	2013
Net (loss) income	$(39,119)	$4,410	$(42,572)
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(26)	-	-
Net change in unrealized loss on auction rate securities	-	192	68
Total other comprehensive (loss) income	(26)	192	68
Comprehensive (loss) income	(39,145)	4,602	(42,504)
Comprehensive loss attributable to noncontrolling interests	(7)	-	-
Comprehensive (loss) income attributable to Progenics	$(39,138)	$4,602	$(42,504)

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2015, 2014 and 2013
(amounts in thousands)

	Common Stock					Treasury Stock			
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Shares	Amount	Noncontrolling Interests	Total
Balance at December 31, 2012	46,765	$ 61	$493,613	$ (424,105)	$ (260)	(200)	$(2,741)	$ -	$66,568
Net loss	-	-	-	(42,572)	-	-	-	-	(42,572)
Other comprehensive income	-	-	-	-	68	-	-	-	68
Compensation expenses for share-based payment arrangements	-	-	3,546	-	-	-	-	-	3,546
Acquisition of subsidiary, net of issuance costs	4,472	6	11,214	-	-	-	-	-	11,220
Sale of common stock in public offering, net of underwriting discounts and commissions ($2,581) and offering expenses ($351)	9,775	12	40,066	-	-	-	-	-	40,078
Forfeitures of restricted stock	(1)	-	-	-	-	-	-	-	-
Exercise of stock options	14	-	71	-	-	-	-	-	71
Balance at December 31, 2013	61,025	79	548,510	(466,677)	(192)	(200)	(2,741)	-	78,979
Net income	-	-	-	4,410	-	-	-	-	4,410
Other comprehensive income	-	-	-	-	192	-	-	-	192
Compensation expenses for share-based payment arrangements	-	-	3,523	-	-	-	-	-	3,523
Sale of common stock in public offering, net of underwriting discounts and commissions ($2,415) and offering expenses ($376)	8,750	12	37,447	-	-	-	-	-	37,459
Acquisition of subsidiary escrow shares returned	(19)	-	(82)	-	-	-	-	-	(82)
Exercise of stock options	77	-	428	-	-	-	-	-	428
	69,833	91	589,826	(462,267)	-	(200)	(2,741)	-	124,909

Balance at December 31, 2014									
Net loss	-	-	-	(39,112)	-	-	-	(7)	(39,119)
Acquisition of subsidiary	-	-	-	-	-	-	-	504	504
Purchase of noncontrolling interests	-	-	-	-	-	-	-	(292)	(292)
Other comprehensive loss	-	-	-	-	(26)	-	-	-	(26)
Compensation expenses for share-based payment arrangements	-	-	2,948	-	-	-	-	-	2,948
Exercise of stock options	313	-	1,737	-	-	-	-	-	1,737
Balance at December 31, 2015	70,146	$ 91	$594,511	$(501,379)	$ (26)	(200)	$(2,741)	$ 205	$90,661

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

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PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net (loss) income	$(39,119)	$4,410	$(42,572)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	565	545	939
(Gains) losses on sales of fixed assets	(2)	(110)	204
Intangible impairment charge	-	2,676	919
Deferred income tax	(133)	(989)	(362)
Change in contingent consideration liability	1,600	1,500	(200)
Expenses for share-based compensation awards	2,948	3,523	3,546
Acquisition of subsidiary escrow shares returned	-	(82)	-
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(3,415)	2,770	4,114
(Increase) decrease in other current assets	(3,058)	(572)	336
(Increase) decrease in deferred tax and other assets	(1,535)	-	2,044
Increase (decrease) in accounts payable and accrued expenses	2,152	58	(1,956)
(Decrease) in deferred revenue – current	-	-	(886)
(Decrease) in deferred tax and other current liabilities	(60)	-	(2,069)
(Decrease) in other liabilities	(80)	(3)	(164)
Net cash (used in) provided by operating activities	(40,137)	13,726	(36,107)
Cash flows from investing activities:			
Acquisition of subsidiary, net of cash acquired	(6,202)	-	-
Cash acquired in acquisition of subsidiary	-	-	1,888
Capital expenditures	(370)	(714)	(137)
Proceeds from sales of fixed assets	48	143	174
Proceeds from redemption of auction rate securities	-	2,400	1,100
Net cash (used in) provided by investing activities	(6,524)	1,829	3,025
Cash flows from financing activities:			
Purchase of noncontrolling interests	(292)	-	-
Equity issuance costs in connection with acquisition of subsidiary	-	-	(45)
Proceeds from public offering of common stock, net of underwriting discounts and commissions and offering expenses	-	37,459	40,078
Proceeds from the exercise of stock options	1,737	428	71
Net cash provided by financing activities	1,445	37,887	40,104
Effect of exchange rate changes on cash	17	-	-
Net (decrease) increase in cash and cash equivalents	(45,199)	53,442	7,022
Cash and cash equivalents at beginning of period	119,302	65,860	58,838
Cash and cash equivalents at end of period	$74,103	$119,302	$65,860
Supplemental disclosure of cash flow information:			
Contingent consideration liability			$$15,700
Stock acquisition consideration			$$11,265

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

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

1. Organization and Business

Progenics Pharmaceuticals, Inc. ("Progenics," "we" or "us") develops innovative medicines and other products for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA®, 1095 and PSMA ADC), and imaging agents (1404 and PyL) intended to enable clinicians and patients to accurately visualize and manage their disease. In addition, as part of its acquisition of EXINI Diagnostics AB ("EXINI") in late 2015, Progenics acquired the EXINI Bone BSI bone scan index product, which is approved for use in Europe, Japan and the U.S. (though not yet available in the U.S.). EXINI Bone BSI is an analytical tool that employs an artificial intelligence-based approach to apply techniques of statistical analysis and pattern recognition to quantify the information produced by bone scintigraphy (bone scan) images used to view cancer present in the skeleton. The EXINI Bone BSI tool "reads" bone scans and produces a standard, automated Bone Scan Index quantification.

We licensed our first commercial drug, RELISTOR® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation ("OIC"), to Salix Pharmaceuticals, Inc.(a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc. ("Valeant")). In June 2015, a New Drug Application for oral RELISTOR (methylnaltrexone bromide) Tablets was submitted by Valeant to the U.S. Food and Drug Administration ("FDA") for the treatment of OIC in adult patients with chronic non-cancer pain. In September 2015, the FDA assigned this New Drug Application for oral RELISTOR a Prescription Drug User Fee Act action date of April 19, 2016. In September 2014 RELISTOR received an expanded approval from the U.S. Food and Drug Administration for the treatment of OIC in patients taking opioids for chronic non-cancer pain. We have partnered other internally-developed or acquired compounds and technologies with third parties. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving proprietary research, development and clinical programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

Our current principal sources of revenue from operations are royalty, development and commercial milestones and sublicense revenue-sharing payments from Valeant's RELISTOR operations. Royalty and milestone payments from RELISTOR depend on success in development and commercialization, which is dependent on many factors, such as Valeant's efforts, decisions by the FDA and other regulatory bodies, competition from drugs for the same or similar indications, and the outcome of clinical and other testing of RELISTOR. In 2014, we recognized a $40 million milestone payment from Valeant related to market approval for subcutaneous RELISTOR.

We have historically funded our operations to a significant extent from capital-raising. During 2014, we raised $37.5 million in an underwritten public offering of 8.75 million shares of common stock at a public offering price of $4.60 per share, and entered into an agreement with an investment bank under which we may sell from time to time up to $50 million of our stock. During 2013, we completed an underwritten public offering of 9.8 million shares of common stock at a public offering price of $4.40 per share, resulting in net proceeds of approximately $40.1 million.

Progenics commenced principal operations in 1988, became publicly traded in 1997 and throughout has been engaged primarily in research and development efforts, establishing corporate collaborations and related activities. Certain of our intellectual property rights are held by wholly owned subsidiaries. All of our U.S. operations are conducted at our facilities in Tarrytown, New York, and our international operations are conducted at our facilities in Lund, Sweden. We operate under a single research and development segment.

Funding and Financial Matters. At December 31, 2015, we held $74.1 million in cash and cash equivalents, a decrease of $45.2 million from $119.3 million at December 31, 2014. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We expect to require additional funding in the future, the availability of which is never guaranteed and may be uncertain. We expect that we may continue to incur operating losses for the foreseeable future.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
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, the Company evaluates its estimates, including but not limited to those related to collectability of receivables, intangible assets and 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. Certain expense amounts have been combined in prior periods' financial statements to conform to the current year presentation.

Consolidation

The consolidated financial statements include the accounts of Progenics and its wholly-owned and controlled subsidiaries as of and for the years ended December 31, 2015, 2014 and 2013. Consolidation of a subsidiary begins when Progenics obtains control over the subsidiary and ceases when Progenics loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed during the year are included in the consolidated financial statements from the date Progenics gains control until the date Progenics ceases to control the subsidiary. Profit or loss and each component of Other Comprehensive Income are attributed to the equity holders of Progenics and to the noncontrolling interests. All significant intercompany balances and transactions have been eliminated in consolidation. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

Revenue Recognition

We recognize revenue from all sources based on the provisions of the SEC's Staff Accounting Bulletin (SAB) No. 104 (SAB 104) and ASC 605 Revenue Recognition. Under ASC 605, delivered items are separate units of accounting, provided (i) the delivered items have value to a collaborator on a stand-alone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered items is considered probable and substantially in our control. A separate update to ASC 605 provides guidance on the criteria that should be met when determining whether the milestone method of revenue recognition is appropriate.

If we are involved in a steering or other committee as part of a multiple-deliverable arrangement, we assess whether our involvement constitutes a performance obligation or a right to participate. For those committees that are deemed obligations, we will evaluate our participation along with other obligations in the arrangement and will attribute revenue to our participation through the period of our committee responsibilities. We recognize revenue for payments that are contingent upon performance solely by our collaborator immediately upon the achievement of the defined event if we have no related performance obligations. Reimbursement of costs is recognized as revenue provided the provisions of ASC 605 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue. Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term.

Royalty revenue is recognized in the period the sales occur, provided the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the

arrangement providing for the royalty. Royalty loss is recognized based upon reported sales deductions in excess of gross sales resulting in net sales (losses) and is recognized in the period net sales (losses) occur. Royalty loss is classified in royalty income in the consolidated statements of operations and the related accrued royalty loss liability is classified in accounts payable and accrued expenses in the consolidated balance sheets.

During the past three years, we also recognized revenue from sales of research reagents and during 2013 from government research grants, awarded to us by the National Institutes of Health (NIH), which we used in proprietary research programs. NIH grant revenue is recognized as efforts are expended and as related program costs are incurred. We performed work under the NIH grants on a best-effort basis.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
In January 2016, Valeant entered into a distribution agreement with Swedish Orphan Biovitrum AB (publ), also known as Sobi, for RELISTOR in Western Europe, Russia, Greece.

During the fourth quarter of 2015 we recognized $1.5 million milestone revenue under our agreement with CytoDyn Inc. as a result of CytoDyn dosing of the first patient in its Phase 3 clinical trial of PRO 140. We are eligible for future milestone and royalty payments.

During 2014 we recognized $40.0 million milestone revenue from Valeant upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients and $1.0 million milestone revenue from FUJIFILM RI Pharma ("Fuji") upon execution of the first contract by Fuji with an investigation site for a Phase 1 trial of 1404 in Japan.

During the third quarter of 2014, Valeant entered into an agreement with Lupin Limited for distribution of RELISTOR in Canada. To date, we did not recognize any revenue related to this agreement, since terms of the Valeant and Progenics negotiations were not fixed and determinable.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, maintenance of research equipment, costs related to research collaboration and licensing agreements, the purchase of in-process research and development, the cost of services provided by outside contractors, including services related to our clinical trials, the full cost of manufacturing drug for use in research, pre-clinical development and clinical trials. All costs associated with research and development are expensed as incurred.

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.

Use of Estimates

Significant estimates include useful lives of fixed assets, the periods over which certain revenues and expenses will be recognized, including collaboration revenue recognized from non-refundable up-front licensing payments and expense recognition of certain clinical trial costs which are included in research and development expenses, the amount of non-cash compensation costs related to share-based payments to employees and non-employees and the periods over which those costs are expensed, the likelihood of realization of deferred tax assets and the assumptions used in the valuations of in-process research and development and contingent consideration liability.

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

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

Net (Loss) Income Per Share

We prepare earnings per share (EPS) data in accordance with ASC 260 Earnings Per Share. Basic net (loss) income per share amounts have been computed by dividing net (loss) income attributable to Progenics by the weighted-average number of common shares outstanding during the period. For 2015 and 2013, we reported net losses and, therefore, potential common shares, amounts of unrecognized compensation expense and windfall tax benefits have been excluded from diluted net loss per share since they would be anti-dilutive. For 2014, we reported net income, and the computation of diluted earnings per share is based upon the weighted-average number of our common shares and dilutive effect, determined using the treasury stock method, of potential common shares outstanding including amounts of unrecognized compensation expense. In periods where shares to be issued upon the assumed conversion of the contingent consideration liability have an anti-dilutive effect on the calculation of diluted earnings per share, these shares are excluded from the calculation.

Concentrations of Credit Risk

Financial instruments which potentially subject Progenics to concentrations of risk consist principally of cash, cash equivalents, auction rate securities and receivables. We invest our excess cash in money market funds. 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, 2015 and 2014, we have invested approximately $62,855 and $112,808, respectively, in cash equivalents in the form of money market funds with one major investment company and held approximately $11,248 and $6,494, respectively, in three commercial banks.

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, which at December 31, 2015 and 2014 was $10 and $10, respectively.

Auction Rate Securities

In accordance with ASC 320 Investments – Debt and Equity Securities, investments are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income or expense. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other

income or expense. In computing realized gains and losses, we compute the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the securities, adjusted for the amortization of any discount or premium. The fair value of auction rate securities has been estimated based on a three-level hierarchy for fair value measurements. Interest and dividends on securities classified as available-for-sale are included in interest income.

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

During the fourth quarter of 2014, all of the $2,208 auction rate securities remaining at December 31, 2013 were redeemed at par. Valuation of securities is subject to uncertainties that are difficult to predict, such as changes to credit ratings of the securities and/or the underlying assets supporting them, default rates applicable to the underlying assets, underlying collateral value, discount rates, counterparty risk, ongoing strength and quality of market credit and liquidity and general economic and market conditions. The valuation of the auction rate securities we held was based on an internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. Due to the settlement of auction rate securities at par in the fourth quarter of 2014, the temporary impairment amount decreased $192.

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 the 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, 2015 or 2014.

Fair Value Measurements

In accordance with ASC 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 assets constituting our available-for-sale portfolio and to our contingent consideration liability arising from the Molecular Insight Pharmaceuticals, Inc. ("Molecular Insight") acquisition based on our assessment of the transparency and reliability of the inputs used in the valuation. ASC 820 defines the three hierarchy levels as:

· Level 1 - Valuations based on unadjusted quoted market prices in active markets for identical securities.

· Level 2 - Valuations based on observable inputs other than Level 1 prices, such as quoted prices for similar assets at the measurement date, quoted prices in markets that are not active or other inputs that are observable, either directly

or indirectly.

- Level 3 - Valuations based on unobservable inputs that are significant to the overall fair value measurement, which as noted above involve management judgment.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
Recurring Fair Value Measurements

We believe the carrying amounts of the Company's cash equivalents, accounts receivable, other current assets, other assets and accounts payable and accrued expenses approximated their fair values as of December 31, 2015 and 2014.

The fair value of the contingent consideration liability, consisting of future potential milestone payments related to the Molecular Insight acquisition was $18.8 million and $17.2 million as of December 31, 2015 and 2014, respectively. The fair value of the contingent consideration liability is categorized as a Level 3 instrument, as displayed in Note 4. The Company records the contingent consideration liability at fair value with changes in estimated fair values recorded in the Consolidated Statements of Operations. During 2015, we reassessed the fair value of the contingent consideration and recorded a $1.6 million increase, primarily due to decrease in discount period and an increase in the risk-free rate. The December 31, 2015 contingent consideration of $18.8 million results from probability adjusted discounted cash flows and Monte Carlo simulation models which include estimates of significant milestone payments to former Molecular Insight stockholders under the acquisition agreement ranging from 2019 to 2025 and risk adjusted discount rates of 10% and 3.5% for the milestone-based and net sales targets, respectively. During 2014, we reassessed the fair value of the contingent consideration and recorded a $1.5 million increase primarily due to higher probability of success for 1404, partially offset by a decrease due to lower projected revenues for MIP-1095.

Nonrecurring Fair Value Measurements

The Company's non-financial assets, such as intangible assets and property and equipment, are measured and recorded at fair value on the acquisition date, and if indicators of impairment exist, we assess recoverability by measuring the amount of any impairment by comparing the carrying value of the asset to its then-current estimated fair value (for intangible assets) or to market prices for similar assets (for property and equipment). If the carrying value is not recoverable we record an impairment charge in the Consolidated Statements of Operations. No impairments occurred for the year ended December 31, 2015. The company reassessed the value of the indefinite lived intangible assets and recorded a non-cash charge to earnings of $2,676 and $919 in 2014 and 2013, respectively. These impairments were the result of changes in the Level 3 assumptions as follows: the timing of beginning cash inflows from 2021 to 2024 and a decrease in discount rate from 20% to 13.5% for the MIP-1095 intangible asset, in addition to the third quarter 2014 and fourth quarter 2013 impairments of the ONALTA™ indefinite-lived and finite-lived intangible assets, resulting from decreased probabilities of success. In connection with the second quarter 2013 amendment of the Company's Tarrytown lease, we recognized impairment losses of $347 on leasehold improvements and machinery and equipment removed from service, which are included in research and development expenses in our accompanying Consolidated Statements of Operations for the year ended December 31, 2013.

Other current assets are comprised of prepaid expenses, interest and other receivables of $5,639 and $2,515 at December 31, 2015 and 2014, respectively, which are expected to be settled within one year. Restricted cash, included in other assets, of $1,692 at December 31, 2015 and $157 at December 31, 2014 represents collateral for letters of credit securing lease obligations. We believe the carrying value of these assets approximates fair value and are considered Level 1 assets.

Fixed Assets

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

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

Deferred Lease Liability and Incentive

Our lease agreements include fixed escalations of minimum annual lease payments and we recognize rental expense on a straight-line basis over the lease terms and record the difference between rent expense and current rental payments as deferred lease liability. Deferred lease incentive includes a construction allowance from our landlord which is amortized as a reduction to rental expense on a straight-line basis over the lease term. As of December 31, 2015 and 2014, the Consolidated Balance Sheets include the following:

	2015	2014
Other current liabilities:		
Deferred lease incentive	$115	$115
Other liabilities:		
Deferred lease liability	$402	$336
Deferred lease incentive	460	575

Income Taxes

We account for income taxes in accordance with the provisions of ASC 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.

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In accordance with ASC 718 Compensation – Stock Compensation and ASC 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).

Uncertain tax positions are accounted for in accordance with ASC 740 Income Taxes, 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 percent 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 percent 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).

Risks and Uncertainties

We have to date relied principally on external funding, collaborations with Valeant, Fuji and others, out-licensing and asset sale arrangements, royalty and product revenue 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 Valeant and Fuji fulfilling their manufacturing obligations, either on their own or through third-party suppliers. For 2015, 2014 and 2013, the primary sources of our revenues were royalty and milestone payments. There can be no assurance that such revenues will continue. Substantially all of our accounts receivable at December 31, 2015 and 2014 were from the above-named sources.

Foreign Currency Translation

Our international subsidiaries generally consider their local currency to be their functional currency. Assets and liabilities of these international subsidiaries are translated into U.S. dollars at year-end exchange rates and revenues and expenses are translated at average exchange rates during the year. Foreign currency translation adjustments for the year are included in other comprehensive income or loss in the consolidated statements of comprehensive (loss) income, and the cumulative effect is included in the stockholders' equity section of the consolidated balance sheets. Realized gains and losses from currency exchange transactions are recorded in operating expenses in the consolidated statements of operations and were not material to our consolidated results of operations in 2015, 2014 or 2013.

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Comprehensive Income (Loss)

Comprehensive income (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) income includes net (loss) income adjusted for the changes in foreign currency translation adjustment and net change in unrealized loss on auction rate securities. The disclosures required by ASC 220 Comprehensive Income for 2015, 2014 and 2013 have been included in the Consolidated Statements of Comprehensive (Loss) Income. There was no income tax expense/benefit allocated to any component of Other Comprehensive (Loss) Income (see Note 13).

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. The Company records 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 the Company records that amount as an accrual. If no amount within the range is a reasonable estimate, then the Company records 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.

Impact of Recently Issued and Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02 ("ASU 2016-02"), Leases (Topic 842), which requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. We are currently evaluating the impact of this new standard on our consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The standard requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and separate presentation of financial assets and financial liabilities by measurement category and form of financial asset. Additionally, the standard eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value of financial instruments. The amendment is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Other than an amendment relating to presenting in comprehensive income the portion of the total change in the fair value of a liability resulting from a change in instrument-specific credit risk (if the entity has elected to measure the liability at fair value), early adoption is not permitted. We are evaluating the impact that this guidance will have on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17 ("ASU 2015-17"), Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The standard requires that deferred tax assets and liabilities be classified as noncurrent on the balance sheet rather than being separated into current and noncurrent. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and

liabilities. We early adopted ASU 2015-17 during fiscal year 2015 on a prospective basis. Accordingly, we have classified all deferred taxes as noncurrent on our December 31, 2015 Consolidated Balance Sheet.

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In September 2015, the FASB issued ASU No. 2015-16 ("ASU 2015-16"), Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. This amendment requires the acquirer in a business combination to recognize in the reporting period in which adjustment amounts are determined any adjustments to provisional amounts that are identified during the measurement period, calculated as if the accounting had been completed at the acquisition date. Prior to the issuance of ASU 2015-16, an acquirer was required to restate prior period financial statements as of the acquisition date for adjustments to provisional amounts. The amendments in ASU 2015-16 are to be applied prospectively upon adoption. We do not expect the adoption of ASU 2015-16 to have a material effect on our consolidated financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which provides a single model for revenue arising from contracts with customers and supersedes current revenue recognition guidance. This ASU provides that an entity should recognize revenue to depict transfers of promised goods or services to customers in amounts reflecting the consideration to which the entity expects to be entitled in the transaction by: (1) identifying the contract; (2) identifying the contract's performance obligations; (3) determining the transaction price; (4) allocating the transaction price to the performance obligations; and (5) recognizing revenue when or as the entity satisfies the performance obligations. The ASU will be effective for annual reporting periods beginning after December 15, 2016, including interim periods. In August 2015, the FASB issued an ASU deferring the effective date by one year, for interim and annual reporting periods beginning after December 15, 2017. Early adoption will be permitted for annual reporting periods beginning after December 15, 2016 and interim periods therein. The guidance permits companies to apply the requirements either retrospectively to all prior periods presented or in the year of adoption through a cumulative adjustment. We are evaluating which transition approach to use and the impact of this ASU on our consolidated financial statements.

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

3. Acquisitions, Goodwill and Acquired Intangible Assets

Acquisition of EXINI

On November 12, 2015, we acquired 92.45% of the outstanding shares of EXINI, a leader in the development of advanced imaging analysis tools and solutions for medical decision support, through a public tender offer to the shareholders of EXINI. EXINI's operations are included in the Consolidated Financial Statements beginning November 12, 2015, the date we acquired control. Through the end of the extended acceptance period of November 20, 2015, we have acquired additional outstanding shares and as of December 31, 2015 we own 96.81% of the voting shares of EXINI. We have commenced a judicial process in Sweden for acquiring the remaining shares and EXINI was delisted and ceased to be publicly traded effective as of the close of trading on December 4, 2015.

EXINI, headquartered in Lund, Sweden, is expected to complement Progenics's strategy to support its imaging and therapeutic agents with sophisticated analytical tools and other technologies that help physicians and patients visualize, understand, target and treat cancer. The acquisition provides us with in-house development capabilities in these areas that we can apply to our own pipeline, including our prostate cancer imaging agents 1404 and PyL.

During the year ended December 31, 2015, the Company incurred $391 in transaction costs related to the acquisition, which primarily consisted of legal, accounting and valuation-related expenses. The transaction costs were recorded in general and administrative expenses in the accompanying consolidated statements of operations. EXINI's business contributed $76 of revenues and $210 of net loss for the period from November 12, 2015 to December 31, 2015.

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Purchase Price Allocation: We have accounted for the EXINI acquisition as a business combination by allocating the consideration we paid to the fair values of the assets acquired, liabilities assumed and noncontrolling interests at the effective date of the acquisition. Acquired intangible assets, including goodwill, are not deductible for tax purposes.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date.

	Amount
Cash and cash equivalents	$ 7
Accounts receivable	18
Other current assets	108
Fixed assets	22
Accounts payable and accrued expenses	(807)
Other current liabilities	(127)
Intangible assets – technology	2,120
Total identifiable net assets	1,341
Noncontrolling interests	(504)
Goodwill	5,372
Total consideration transferred	$ 6,209

The replacement cost method, a variation of the cost approach, was applied to assess the value of the technology asset 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.

Our approach to valuing the acquired technology asset was to determine the total employee cost and effort required to replicate the technology asset in the state it existed at the acquisition date. In determining the total all-inclusive, fully-burdened employee cost to replicate the technology asset, we determined that it would take approximately four years of five senior employees working full-time to recreate the technology asset of similar utility. We then took the present value, discounted at 3.5%, of the total fully-burdened annual cost of these senior employees (including annual salary, bonuses, and benefits) to arrive at a total employee cost to recreate the technology asset acquired of $2,120. Based on our assessment of the acquired technology functionality, rate of technological change in the industry and in our Company, as well as our experience with similar technology assets, we expect the remaining useful life for this acquired asset to be approximately 10 years.

The noncontrolling interests were calculated based on the quoted share price of EXINI as of the acquisition date times the quantity of shares that constituted the noncontrolling interests.

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Goodwill and Acquired Intangible Assets

In connection with the 2015 acquisition of EXINI and the 2013 acquisition of Molecular Insight, intangible assets and goodwill were initially measured at the acquisition date at estimated fair value and capitalized.

Third and fourth quarter 2014 reviews of our Molecular Insight intangible assets resulted in $2,660 impairments of the indefinite-lived balance and a $16 impairment of the finite-lived balance, with the corresponding impairment charges recorded in the Consolidated Statements of Operations.

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

	Goodwill	IPR&D	Finite-lived intangible assets
Balance at January 1, 2014	$ 7, 702	$ 31,360	$ 19
Amortization expense	-	-	(3)
Impairment	-	(2,660)	(16)
Balance at December 31, 2014	$ 7,702	$ 28,700	-
Increase related to EXINI acquisition	5,372	-	2,120
Amortization expense	-	-	(27)
Impairment	-	-	-
Balance at December 31, 2015	$ 13,074	$ 28,700	$ 2,093

The following table reflects the components of the finite-lived intangible assets as of December 31, 2015:

	Gross Amount	Accumulated Amortization	Net Carrying Value
Finite lived intangible assets	$ 2,120	$ 27	$ 2,093
Total	$ 2,120	$ 27	$ 2,093

The weighted-average remaining life of the finite-lived intangible assets was approximately ten years at December 31, 2015.

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Amortization expense was calculated on a straight-line basis over the estimated useful life of the asset and was $27 and $3 for the year ended December 31, 2015 and 2014, respectively.

4. Fair Value Measurements

The change in the fair value of our auction rate securities was recorded as a component of other comprehensive (loss) income in accordance with ASC 320 Investments – Debt and Equity Securities in 2013. We also record the contingent consideration liability resulting from the Molecular Insight acquisition at fair value in accordance with ASC 820-10-50.

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

		Fair Value Measurements at December 31, 2015		
	Balance at December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 62,855	$62,855	$ -	$ -
Total Assets	$ 62,855	$62,855	$ -	$ -
Liability:				
Contingent consideration	$ 18,800	$-	$ -	$ 18,800
Total Liability	$ 18,800	$-	$ -	$ 18,800

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

Liability:				
Contingent consideration	$17,200	$-	$ -	$ 17,200
Total Liability	$17,200	$-	$ -	$ 17,200

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The estimated fair value of the contingent consideration liability of $18,800 as of December 31, 2015, represents future potential milestone payments to former Molecular Insight stockholders. The Company considers this liability a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value was determined based on probability adjusted discounted cash flow and Monte Carlo simulation models that included significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs were the probabilities of achieving regulatory approval of the development projects and subsequent commercial success, and discount rates.

Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively. The Company records the contingent consideration liability at fair value with changes in estimated fair values recorded in change in contingent consideration liability in the Consolidated Statements of Operations.

The following tables present quantitative information pertaining to the December 31, 2015 and 2014 fair value measurements of the Level 3 inputs. The 2015 increase in the contingent consideration liability of $1,600 resulted primarily from a decrease in the discount period, a 0.2% increase in the risk-free rate and a 5% increase in asset volatility which affects the probability adjusted cash flow.

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

Period of milestone expected achievement	2019 – 2025
Discount rates[1]	12% / 3.5%

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	Fair Value as of December 31, 2014	Valuation Technique	Unobservable Input	Range (Weighted Average)
Contingent consideration liability:				
AZEDRA commercialization	$ 2,300	Probability adjusted discounted cash flow model	Probability of success	40%
			Period of milestone expected achievement	2018
			Discount rate	10%
1404 commercialization	$ 3,800	Probability adjusted discounted cash flow model	Probability of success	59%
			Period of milestone expected achievement	2019
			Discount rate	10%
MIP-1095 commercialization	$ 400	Probability adjusted discounted cash flow model	Probability of success	19%
			Period of milestone expected achievement	2023
			Discount rate	10%
Net sales targets	$ 10,700	Monte-Carlo simulation	Probability of success	19% - 59% (37.4%)
			Period of milestone expected achievement	2019 - 2026
			Discount rate[1]	12% / 3.5%

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

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

	Liability – Contingent Consideration Fair Value Measurements Using Significant Unobservable Inputs

	(Level 3)	
Description	2015	2014
Balance at beginning of period	$17,200	$15,700
Fair value adjustment to contingent consideration included in net (loss) income	1,600	1,500
Balance at end of period	$18,800	$17,200
Changes in unrealized gains or losses for the period included in earnings (or changes in net assets) for liabilities held at the end of the reporting period	$1,600	$1,500

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5. Accounts Receivable

Our accounts receivable represent amounts due to Progenics from collaborators, royalties and the sales of research reagents, and as of December 31, 2015 and 2014, consisted of the following:

	2015	2014
Collaborators	$63	$14
Royalties	3,463	40
Other	27	65
	3,553	119
Less, allowance for doubtful accounts	(10)	(10)
Total	$3,543	$109

6. Fixed Assets

Fixed assets as of December 31, 2015 and 2014 consisted of the following:

	2015	2014
Computer equipment	$1,727	$1,784
Machinery and equipment	5,706	5,238
Furniture and fixtures	131	116
Leasehold improvements	5,027	5,027
Other	87	208
	12,678	12,373
Less, accumulated depreciation and amortization	(10,271)	(9,821)
Total	$2,407	$2,552

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At December 31, 2015 and 2014, $1.5 million and $1.8 million, respectively, of leasehold improvements, net were being amortized over periods of 6.4-10.8 years, under leases with terms through December 31, 2020.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2015 and 2014, consisted of the following:

	2015	2014
Accrued consulting and clinical trial costs	$2,960	$2,662
Accrued payroll and related costs	1,845	1,722
Legal and professional fees	3,605	1,063
Accounts payable and other	452	1,040
Other	682	83
Total	$9,544	$6,570

8. Restructuring

We incurred a $0.4 million headcount reduction restructuring obligation in the first quarter of 2014, which was fully paid as of the end of the third quarter 2014. A first quarter 2013 headcount reduction resulted in a $1.5 million restructuring obligation paid that year. During the second quarter of 2013, we incurred other exit and contract termination costs, including in connection with termination of a Molecular facilities lease ($0.9 million) and amendment and consolidation of the Company's facilities lease ($0.5 million).

Activity in the restructuring accrual, which is included in accounts payable and accrued expenses in our Consolidated Balance Sheets, and in research and development and general and administrative expenses in the Consolidated Statements of Operations, is specified below.

	Severance and Related Benefits	Other Exit Costs	Contract Termination Costs	Total Restructuring Accrual
Balance at December 31, 2012	$ 813	$ -	$ -	$ 813
Additions, net	1,492	15	1,359	2,866
Payments	(2,305)	(15)	(1,359)	(3,679)
Balance at December 31, 2013	-	-	-	-
Additions, net	359	-	-	359
Payments	(359)	-	-	(359)
Balance at December 31, 2014 and 2015	$ -	$ -	$ -	$ -

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9. Stockholders' Equity

We are authorized to issue 160.0 million shares of Common Stock, par value $.0013, and 20.0 million shares of preferred stock, par value $.001. The Board of Directors has the authority to issue common and preferred shares, in series, with rights and privileges as determined by the Board of Directors. In the first quarter of 2014 we raised $37,459 in an underwritten public offering of 8,750 shares of common stock, and entered into an agreement with an investment bank under which we may sell from time to time up to $50,000 of our stock. In July 2013 we completed a public offering of 9,775 shares of common stock, with net proceeds of approximately $40,078.

10. Commitments and Contingencies

a. Operating Leases

At December 31, 2015, we leased laboratory and office space in Tarrytown, New York, pursuant to lease agreements expiring in December 2020 (subject to an early termination right), and additional office space in Lund, Sweden.

On December 31, 2015, in connection with its decision to relocate its headquarters, the Company entered into a lease for office space located in New York City expiring on September 30, 2030. The Company intends to use the leased premises as its headquarters and expects the lease term to commence in the second half of 2016.

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

As of December 31, 2015, future minimum annual payments under all operating lease agreements are as follows:

Years ending December 31,	Minimum Annual Payments
2016	$ 2,024
2017	3,825
2018	3,907
2019	3,901
2020	3,987
Thereafter	22,567
Total	$ 40,211

Rental expense totaled approximately $1,864, $1,864 and $3,548 for 2015, 2014 and 2013, respectively. For 2015, 2014 and 2013, amounts paid exceeded rent expense by $49, $3 and $164, respectively, due to the recognition of lease incentives. Additional facility charges, including utilities, taxes and operating expenses, for 2015, 2014 and 2013 were approximately $2,456, $2,117 and $2,330, respectively.

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(amounts in thousands, except per share amounts or as otherwise noted)
b. Licensing, Service and Supply Agreements

Progenics and its subsidiaries 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 $388, $498 and $567 during the last three years, respectively.

	Paid from inception/acquisition to December 31, 2015	Future [1] Commitments	Terms
Seattle Genetics, Inc.	$ 4,601	$ 13,800	Milestone and periodic maintenance payments to use ADC technology to link chemotherapeutic agents to monoclonal antibodies that target prostate specific membrane antigen. ADC technology is based in part on technology licensed by SGI from third parties.
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	353	52,188	Annual minimum royalty payments and milestones to use technology related to PSMA.
University of Zurich and the Paul Scherrer Institute	270	1,070	Annual maintenance and license fee payments, milestones and royalties in respect of licensed technology related to 1404.
University of Western Ontario	27	274	Annual minimum royalty, administration and milestone payments in respect of licensed technology related to AZEDRA.
Johns Hopkins University Technology	150	2,760	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 Molecular Insight licenses and service agreements, as to which we have paid $251 through December 31, 2015, and have future commitments of $14,375, subject to occurrence of future milestones or events.

c. 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 Progenics, 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 $54, $67 and $39 for 2015, 2014 and 2013, respectively. Those expenses include the fair value of stock options granted during 2013, of approximately $6, $17 and $7 for 2015, 2014 and 2013, respectively. Such amounts of fair value are included in research and development expense for each year presented (see Note 11).

d. Related Party Agreement

In December 2012, Progenics entered into a financial advisory agreement with MTS Health Partners, L.P., of which the Company's Board Chair is a Senior Managing Director and partner, whereby, in 2013, MTS received monthly retainers totaling $55 during the term of the agreement and $300 for MTS' services in connection with the Molecular Insight acquisition. This agreement was terminated in June 2013.

e. Legal Proceedings

Progenics is a party to a proceeding brought by a former employee on November 2, 2010 in the U.S. District Court for the Southern District of New York, complaining that Progenics had violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating the former employee. The former employee seeks reinstatement of his employment, compensatory damages and certain costs and fees associated with the litigation. In July 2013, the federal District Court hearing the case issued an order denying our motion for summary judgment dismissing the former employee's complaint. The case went to trial in July 2015 and on July 31, 2015 the jury awarded the former employee approximately $1.66 million in compensatory damages (held in escrow by the District Court as restricted cash and recorded in other current assets) primarily consisting of salary the former employee would have received during the period from his termination to the date of the verdict. We have accrued an amount in connection with this matter which we believe is probable and estimable. Certain ancillary matters in the case, including the former employee's claims for additional compensation, pre-judgment interest and the awarding of attorneys' fees, remain subject to dispute. Given that there are matters yet to be decided and an estimate of the additional exposure, if any, has yet to be determined there is a reasonable possibility that additional losses may be incurred. Progenics has moved for a new trial or, in the alternative, for remittitur and continues to assess the verdict and its options in the case, including a potential appeal.

In July 2015, Progenics was named as a defendant in a complaint brought by Lonza Sales AG ("Lonza") in the U.S. District Court for the District of Delaware arising from a multi-product license agreement entered into by Progenics and Lonza in April 2010. The complaint alleged that Progenics breached the multi-product license agreement and misappropriated trade secrets in connection with Progenics' sale of certain assets relating to the PRO 140 product to a third party, and sought unspecified damages and injunctive relief. On November 3, 2015, the District Court of Delaware denied Progenics' motion to dismiss the case. On November 17, 2015, Progenics answered Lonza's complaint and brought certain counterclaims against Lonza. On February 9, 2016, Progenics and Lonza agreed to settle and release their respective claims and to dismiss the litigation and, on February 19, 2016, the case was dismissed by the United States District Court for the District of Delaware. Other than the granting of the mutual releases, no consideration or damages were paid by either party to the other in connection with the settlement of the litigation.

On October 7, 2015 Progenics, Valeant and Wyeth LLC received notification of a Paragraph IV certification for certain patents for RELISTOR® (methylnaltrexone bromide) subcutaneous injection, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certification resulted from the filing by Mylan Pharmaceuticals, Inc. of an Abbreviated New Drug Application ("ANDA") with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of these patents expire.

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

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

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

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

Each of the above-described proceedings is in its early stages and Progenics and Valeant continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between Progenics and Valeant, Valeant has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement.

Progenics and its affiliates 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 the Company, its results of operations, financial condition and cash flows.

In the third quarter of 2014, Progenics and Ono, its former licensee of RELISTOR in Japan, settled all claims between them relating to an arbitration commenced by Progenics in 2013, the parties' October 2008 License Agreement and the former licensee's development and commercialization of the drug. In connection therewith, the parties exchanged mutual releases and the former licensee paid Progenics $7.25 million, which was recorded as other operating income.

11. Share-Based Payment Arrangements

Our share-based compensation to employees includes non-qualified stock options, restricted stock and shares issued under our Purchase Plans, 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.

Compensation cost for share-based awards will be recognized in our financial statements over the related requisite service periods usually the vesting periods for awards with a service condition. We have made an accounting policy decision to use the straight-line method of attribution of compensation expense, under which the grant date fair value of share-based awards will be recognized on a straight-line basis over the total requisite service period for the total award.

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PROGENICS PHARMACEUTICALS, INC.
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(amounts in thousands, except per share amounts or as otherwise noted)

We have adopted two stock incentive plans, the 1996 Amended Stock Incentive Plan (terminated in 2006) and the 2005 Stock Incentive Plan. Under these Plans as amended, up to 5,000 and 11,450 shares of common stock, respectively, have been reserved for the issuance of awards to employees, consultants, directors and other individuals who render services to Progenics (collectively, Awardees). The Plans contain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment as defined. Each Plan provides for the Board or Committee to grant to Awardees stock options, stock appreciation rights, restricted stock, performance awards or phantom stock, as defined (collectively, Awards). The Committee is also authorized to determine the term and vesting of each Award and the Committee may in its discretion accelerate the vesting of an Award at any time. Stock options granted under the Plans generally vest pro rata over three to five years and have terms of ten years. Restricted stock issued under either Plan generally vested annually over three to five years, unless specified otherwise by the Committee. The exercise price of outstanding non-qualified stock options is usually equal to the fair value of our common stock on the date of grant. The exercise price of non-qualified stock options granted from the 2005 Plan and incentive stock options (ISO) granted from the Plans may not be lower than the fair value of our common stock on the dates of grant. At December 31, 2015, 2014 and 2013, all outstanding stock options were non-qualified options. The 2005 Plan will terminate on March 25, 2024; options granted before termination of the Plans will continue under the respective Plans until exercised, cancelled or expired.

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.

Under ASC 718 Compensation – Stock Compensation, the fair value of each non-qualified stock option award is estimated on the date of grant using the Black-Scholes option pricing model, which requires input assumptions noted in the following table. Ranges of assumptions for inputs are disclosed where the value of such assumptions varied during the related period. 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 it provides the most reliable indication of future volatility. Future volatility is expected to be consistent with historical; historical volatility is calculated using a simple average calculation; historical data is available for the length of the option's expected term and a sufficient number of price observations are used consistently. Since our stock options are not traded on a public market, we do not use implied volatility. For 2015, 2014 and 2013 our expected term was calculated based upon historical data related to exercise and post-termination cancellation activity; accordingly, for grants issued to employees and directors and officers, we are using expected terms of 5.3 and 7.4 years, 5.3 and 7.5 years and 5.3 and 7.4 years, respectively. The expected term for options granted to non-employees was also calculated separately from stock options granted to employees and directors and officers and was ten years, which is the contractual term of those options. We have never paid dividends and do not expect to pay dividends in the future. Therefore, our dividend rate is zero. The risk-free rate for periods within the expected term of the options is based on the U.S. Treasury yield curve in effect at the time of grant. The following table presents assumptions used in computing the fair value of option grants during 2015, 2014 and 2013:

	2015	2014	2013
Expected volatility	74 % – 84%	74 % – 84%	73 % – 90%
Expected dividends	Zero	Zero	Zero
Expected term (years)	5.3 – 7.4	5.3 – 7.5	5.3 – 10
Weighted average expected term (years)	6.04	5.93	5.96

Risk-free rate	1.64 % – 2.35%	1.64 % – 2.42%	0.76 % – 2.83%

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
A summary of option activity under the Plans as of December 31, 2015 and changes during the year then ended is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Yr.)	Aggregate Intrinsic Value
Outstanding at January 1, 2015	5,418	$ 9.96		
Granted	1,127	6.88		
Exercised	(313)	5.54		
Forfeited	(433)	5.76		
Expired	(665)	16.63		
Outstanding at December 31, 2015	5,134	$ 9.05	5.69	$ 2,424
Exercisable at December 31, 2015	3,896	$ 9.97	4.70	$ 1,765

The weighted average grant-date fair value of options granted under the Plans during 2015, 2014 and 2013 was $5.02, $3.41 and $3.74, respectively. The total intrinsic value of options exercised during 2015, 2014 and 2013 was $465, $102 and $11, respectively.

The options granted under the Plans, described above, include non-qualified stock options granted to our former CEO on July 3, 2006. For the 2006 award, the requisite service period is the shortest of the explicit or implied service periods and the explicit service period for this award is nine years and 11 months from the grant date. At December 31, 2015, the estimated requisite service period for the 2006 award was 0.5 years. For 2015, 2014 and 2013, the total compensation expense recognized for the performance-based options was $0.1 million, $0.1 million and $0.1 million, respectively.

The total compensation expense of shares, granted to both employees and non-employees, under all of our share-based payment arrangements that was recognized in operations during 2015, 2014 and 2013 was:

	2015	2014	2013
Recognized as:			
Research and Development	$1,099	$1,843	$2,012
General and Administrative	1,849	1,680	1,534
Total	$2,948	$3,523	$3,546

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
No tax benefit was recognized related to such compensation cost because of the Company's net operating losses and the related deferred tax assets were fully offset by valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the periods presented.

As of December 31, 2015, there was $4.1 million of total unrecognized compensation costs related to non-vested stock options under the 1996 and 2005 Plans. Those costs are expected to be recognized over a weighted average period of 3 years. Cash received from exercises under all share-based payment arrangements for 2015 was $1.7 million. We issue new shares of our common stock upon share option exercises.

12. Employee Savings Plan

The terms of the amended and restated Progenics Pharmaceuticals 401(k) Plan (the Amended Plan), among other things, allow eligible employees to participate in the Amended Plan by electing to contribute to the Amended 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 year ended December 31, 2015 and 50% of employee contributions equal to 5%-8% of compensation during the two years ended December 31, 2014, made by eligible employees to the Amended 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 $327, $276 and $330 to the Amended Plan for 2015, 2014 and 2013, 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.

There is no provision or benefit for federal or state income taxes for 2015, 2014 and 2013, other than $133, $989 and $362 income tax benefit in 2015, 2014 and 2013, respectively, resulting from 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. We have completed calculations through July 15, 2014, under Internal Revenue Code Section 382, the results of which indicate that past ownership changes will limit annual utilization of NOLs in the future. Ownership changes subsequent to July 15, 2014, may further limit the future utilization of net operating loss and tax credit carry-forwards as defined by the federal and state tax codes.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
Deferred tax assets and liabilities as of December 31, 2015 and 2014, consisted of the following:

	2015	2014
Deferred tax assets:		
Depreciation and amortization	$2,215	$5,770
R&E tax credit carry-forwards	19,284	18,612
NYS investment tax credit carry-forwards	1,087	1,090
AMT credit carry-forwards	211	211
Net operating loss carry-forwards	226,639	205,792
Capitalized research and development expenditures	15,149	20,280
Stock compensation	12,250	13,848
Other items	2,562	-
Total gross deferred tax assets	279,397	265,603
Less: Valuation allowance	(279,397)	(265,603)
Deferred tax assets	-	-
Deferred tax liability	(11,199)	(11,332)
Net deferred tax liability	$(11,199)	$(11,332)

We maintain a full 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 2015, 2014 and 2013, we incurred net losses for tax purposes. We recognized a full tax valuation against deferred tax assets at December 31, 2015 and 2014. In 2015 and 2014 we recognized deferred income tax liabilities of $11,199 and $11,332, 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.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
The following is a reconciliation of income taxes computed at the Federal statutory income tax rate to the actual effective income tax provision during 2015, 2014 and 2013:

	2015	2014	2013
U.S. Federal statutory rate	34.0%	34.0%	34.0%
State income taxes, net of Federal benefit	4.8	8.0	5.4
Foreign rate differential	(0.1)	-	-
Research and experimental tax credit	1.7	(16.0)	3.8
Effect of federal and state tax rate changes	(4.8)	1.6	(8.7)
Permanent differences	(1.4)	15.1	0.1
Stock option shortfalls	(6.1)	38.1	(3.8)
New York NOL adjustment	3.8	-	-
Change in valuation allowance	(31.6)	(109.6)	(30.0)
Income tax benefit	0.3%	(28.8)%	0.8%

As of December 31, 2015, we had available, for tax return purposes, unused federal NOLs of approximately $606.4 million, which will expire in various years from 2018 to 2035, $18.2 million of which were generated from deductions post January 1, 2006 that, when realized, will reduce taxes payable and will increase paid-in-capital and are not reflected in our deferred tax assets above. Additionally, $11.0 million of the valuation allowance relates to NOLs attributable to excess tax deductions for equity compensation pre January 1, 2006. When realized this will also be reflected as an increase to paid-in-capital. Also, we had available, for tax return purposes, unused state NOLs of approximately $554.8 million, which will expire in various years from 2030 to 2035.

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 credit carry-forwards. Such a study might result in an adjustment to our research and experimental 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 Molecular Insight acquisition. A full valuation allowance has been provided against the Company's research and experimental 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, 2015, we are subject to federal, foreign and state income tax. Open tax years relate to years in which unused net operating losses were generated or, if used, for which the statute of limitation for examination by taxing authorities has not expired. Our open tax years extend back to 1997. No amounts of interest or penalties were recognized in our Consolidated Statements of Operations or Consolidated Balance Sheets as of and for the years ended December 31, 2015, 2014 and 2013.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
Our research and experimental (R&E) tax credit carry-forwards of approximately $20.0 million at December 31, 2015 expire in various years from 2018 to 2035.

As of December 31, 2015 and 2014, 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, 2015 and 2014.

	2015	2014
Beginning uncertain tax benefits	$2,661	$2,661
Current year - increases	-	-
Current year - decreases	-	-
Settlements	-	-
Expired statuses	-	-
Ending uncertain tax benefits	$2,661	$2,661

14. Net (Loss) Income Per Share

Our basic net (loss) income per share amounts have been computed by dividing net (loss) income attributable to Progenics by the weighted-average number of common shares outstanding during the period. For 2015 and 2013, we reported net losses and, therefore, 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 the 2015 and 2013 periods. For 2014, we reported net income, and the computation of diluted earnings per share is based upon the weighted-average number of our common shares and dilutive effect, determined using the treasury stock method. In applying the treasury stock method for the calculation of diluted EPS, amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted EPS calculation unless they are anti-dilutive. In periods where shares to be issued upon the assumed conversion of the contingent consideration liability have an anti-dilutive effect on the calculation of diluted earnings per share, these shares are excluded from the calculation. 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.

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
The calculations of net (loss) income per share, basic and diluted, are as follows:

	Net (Loss) Income Attributable to Progenics (Numerator)	Weighted Average Common Shares (Denominator)	Per Share Amount
2015:			
Basic and diluted	$ (39,112)	69,716	$ (0.56)
2014:			
Basic	$ 4,410	68,185	$ 0.06
Dilutive effect of contingent consideration liability	-	-	
Dilutive effect of stock options	-	58	
Diluted	$ 4,410	68,243	$ 0.06
2013:			
Basic and diluted	$ (42,572)	55,798	$ (0.76)

During 2015, 2014 and 2013, anti-dilutive common shares excluded from diluted per share amounts consist of the following:

	2015		2014		2013	
	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price
Options	6,381	$ 9.70	5,036	$ 10.56	5,969	$ 11.54
Contingent consideration liability	2,827		3,457		3,544	
Total	9,208		8,493		9,513	

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PROGENICS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued
(amounts in thousands, except per share amounts or as otherwise noted)
15. Unaudited Quarterly Results (unaudited)

Summarized quarterly financial data during 2015 and 2014 are as follows:

	2015 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues [1]	$248	$1,937	$1,396	$5,095
Net loss	(10,254)	(11,697)	(10,014)	(7,154)
Net loss attributable to noncontrolling interests	-	-	-	(7)
Net loss attributable to Progenics	(10,254)	(11,697)	(10,014)	(7,147)
Net loss per share attributable to Progenics - basic	(0.15)	(0.17)	(0.14)	(0.10)
Net loss per share attributable to Progenics - diluted	(0.15)	(0.17)	(0.14)	(0.10)

	2014 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues (losses) [2]	$1,815	$1,477	$41,656	$(571)
Net (loss) income	(9,313)	(11,073)	36,975	(12,179)
Net (loss) income per share - basic	(0.15)	(0.17)	0.53	(0.18)
Net (loss) income per share - diluted	(0.15)	(0.17)	0.51	(0.18)

(1) Revenues in the fourth quarter of 2015 include $1.5 million milestone revenue from CytoDyn.

(2) Revenues in the first and third quarters of 2014 include $1.0 million milestone revenue from Fuji and $40.0 million milestone revenue from Valeant, respectively. Valeant reported sales deductions in excess of gross sales resulting in a royalty loss from net RELISTOR losses during the fourth quarter of 2014, leading us to recognize an accrued royalty loss liability owed to Valeant.

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SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

Allowance for Doubtful Accounts

Year ended December 31, (in thousands)	Beginning Balance	Additions Charged to General and Administrative Expenses	Deductions Accounts Written Off During Period	Ending Balance
2015	$ 10	$ -	$ -	$ 10
2014	$ 7	$ 3	$ -	$ 10

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

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

Date: March 11, 2016

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

Signature	Capacity	Date
/s/ PETER J. CROWLEY Peter J. Crowley	Chairman	March 11, 2016
/s/ PAUL J. MADDON Paul J. Maddon, M.D., Ph.D.	Vice Chairman	March 11, 2016
/s/ MARK R. BAKER Mark R. Baker	Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2016
/s/ KAREN J. FERRANTE Karen J. Ferrante, M.D.	Director	March 11, 2016
/s/ MICHAEL D. KISHBAUCH Michael D. Kishbauch	Director	March 11, 2016
/s/ DAVID A. SCHEINBERG David A. Scheinberg, M.D., Ph.D.	Director	March 11, 2016
/s/ NICOLE S. WILLIAMS Nicole S. Williams	Director	March 11, 2016
/s/ PATRICK FABBIO Patrick Fabbio	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2016

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EXHIBIT INDEX

Exhibit Number *	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(2)	Amended and Restated By-laws of the Registrant.
4.1(3)	Specimen Certificate for Common Stock, $0.0013 par value per share, of the Registrant.
10.5(4) ‡	Amended and Restated 1996 Stock Incentive Plan
10.6.3(5) ‡	Amended 2005 Stock Incentive Plan
10.6.4(6) ‡	Form of Non-Qualified Stock Option Award Agreement
10.6.5(6) ‡	Form of Restricted Stock Award Agreement
10.7(7) ‡	Form of Indemnification Agreement
10.8.2(8) ‡	Retirement Agreement, dated as of March 14, 2012, between the Registrant and Dr. Paul J. Maddon
10.21.1(9)	Amended and Restated Agreement of Lease, dated October 28, 2009, between BMR-Landmark at Eastview LLC and the Registrant.
10.25(10) †	Option and License Agreement, dated May 8, 1985, by and between the University of Chicago and UR Labs, Inc., as amended by (i) Amendment to Option and License Agreement, dated September 17, 1987, by and between the University of Chicago and UR Labs, Inc. and (ii) Second Amendment to Option and License Agreement, dated March 3, 1989, by and among the University of Chicago, ARCH Development Corporation and UR Labs, Inc.
10.26(11)	Membership Interest Purchase Agreement, dated April 20, 2006, between the Registrant Inc. and Cytogen Corporation.
10.27(11) †	Amended and Restated PSMA/PSMP License Agreement, dated April 20, 2006, by and among the Registrant, Cytogen Corporation and PSMA Development Company LLC.
10.34(12) †	Collaboration Agreement, effective June 14, 2005, by and between Seattle Genetics, Inc. and PSMA Development Company, LLC.
10.37(13) †	License Agreement dated as of February 3, 2011, by and between Salix Pharmaceuticals, Inc., the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Excelsior Life Sciences Ireland Limited.
10.37.1(13) †	2010 Agreement Related to Progenics' MNTX In-License, dated February 3, 2011, by and among the University of Chicago, acting on behalf of itself and ARCH Development Corporation, the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Salix Pharmaceuticals, Inc.
10.38(14) †	Stock Purchase and Sale Agreement, dated January 16, 2013, by and between Molecular Insight Pharmaceuticals, Inc., its Stockholders, the Registrant, and Highland Capital Management, L.P., as Stockholders Representative.
10.39(14) †	License Agreement, dated September 1, 2012, by and between FUJIFILM RI Pharma Co., Ltd. and Molecular Insight Pharmaceuticals, Inc.
10.40(15) †	License Agreement, dated May 4, 2012, between Molecular Insight Pharmaceuticals, Inc., the University of Zurich and the Paul Scherrer Institute.
10.41(16)	License Agreement, dated as of December 15, 2000, between Molecular Insight Pharmaceuticals, Inc. and The Board of Governors of the University of Western Ontario.
10.43(17)	Controlled Equity Offering^{SM} Sales Agreement dated as of January 23, 2014, by and between the Registrant and Cantor Fitzgerald & Co.
10.44(18) ‡	Agreement, dated September 19, 2014, between the Registrant and Dr. Hagop Youssoufian.
10.45(12) †	Collaboration Agreement, effective February 21, 2001, by and between Abgenix, Inc. and PSMA Development Company, LLC.
10.46 (19) †	Lease, dated December 31, 2015, between Progenics Pharmaceuticals, Inc. and WTC TOWER 1 LLC.
10.47	License Agreement, dated as of 30 July, 2015 between the Registrant and The Johns Hopkins University.
10.48	Employment Offer Letter Agreement between the Registrant and Sheldon Hirt.

10.49	Employment Offer Letter Agreement between the Registrant and Patrick Fabbio.
12.1	Statement re computation of ratio of earnings (loss) to combined fixed charges and preferred stock dividends.
21.1	Subsidiaries of the Registrant.

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23.1	Consent of Ernst & Young LLP.
31.1	Certification of Mark R. Baker, Chief Executive Officer of the Registrant pursuant to 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Patrick Fabbio, Senior Vice President and Chief Financial Officer of the Registrant pursuant to 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Mark R. Baker, Chief Executive Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Patrick Fabbio, Senior Vice President and Chief Financial Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document

* Exhibits footnoted as previously filed have been filed as an exhibit to the document of the Registrant or other registrant referenced in the footnote below, and are incorporated by reference herein.

(1) Previously filed in Current Report on Form 8-K filed on June 13, 2013.
(2) Previously filed in Current Report on Form 8-K filed on March 16, 2012.
(3) Previously filed in Registration Statement on Form S-1, Commission File No. 333-13627.
(4) Previously filed in Registration Statement on Form S-8, Commission File No. 333-120508.
(5) Previously filed in Current Report on Form 8-K filed on June 18, 2014.
(6) Previously filed in Current Report on Form 8-K filed on July 8, 2008.
(7) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
(8) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.
(9) Previously filed in Current Report on Form 8-K filed on November 28, 2012.
(10) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2005.
(11) Previously filed in Quarterly Report on Form 10-Q for the quarter ended June 30, 2006
(12) Previously filed in Amendment No. 2 to Annual Report on Form 10-K/A for the year ended December 31, 2009.
(13) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.
(14) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.
(15) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2013.
(16) Previously filed in Registration Statement on Form S-1, Commission File No. 333-129570 filed by Molecular Insight Pharmaceuticals, Inc.
(17) Previously filed in Registration Statement on Form S-3, Commission File No. 333-193521.
(18) Previously filed in Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.
(19) Previously filed in Current Report on Form 8-K filed on January 5, 2016.

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

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