

## PROGENICS PHARMACEUTICALS INC

# FORM 10-K (Annual Report)

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

## **FORM 10-K**

(Mark One)

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	For the fiscal year ended December 31, 2014	E SECURITIES EXCHANGE A	CT OF 1934
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF	THE SECURITIES EXCHANG	GE ACT OF 1934 For the
For the fiscal year ended December 31, 2014 Or  TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For transition period from			
	PROGENICS PHARMACI	EUTICALS, INC.	
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  For the fiscal year ended December 31, 2014 Or  TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For transition period from			
	Tarrytown, NY 1	0591	
	Registrant's telephone number, includin	g area code: (914) 789-2800	
	Title of each class	Name of each exchange on	
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  For the fiscal year ended December 31, 2014  Or  TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from			
I	ndicate by check mark if the registrant is a well-known seasoned issuer, as defined	in Rule 405 of the Securities Act.	Yes □ No □
I	ndicate by check mark if the registrant is not required to file reports pursuant to Sec	tion 13 or Section 15(d) of the Act.	Yes □ No □
durin	ig the preceding 12 months (or for such shorter period that the registrant was require		
be su	abmitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chap		
best o	of registrant's knowledge, in definitive proxy or information statements incorporate		
			maller reporting company. See
I	ndicate by check mark whether the registrant is a shell company (as defined in Rule	12b-2 of the Exchange Act). Yes	No 🗆

to

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant on June 30, 2014, based upon the closing price of the Common Stock on The NASDAQ Stock Market LLC on that date of \$4.31 per share, was \$165,112,553 (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 10, 2015, a total of 69,639,949 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 2015 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. When we use the words "anticipates," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. While it is impossible to identify or predict all such matters, these differences 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 appearing 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 products by our partners and the royalty generated thereby; 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 enter into favorable collaboration or other relationships or that existing or future relationships 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 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, or that any of our other programs will result in a commercial product.

We do not have a policy of updating or revising forward-looking statements and we assume no obligation to update 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, that 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 .

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 the Company's 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 Progenics. 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 and Onalta are trademarks of our Molecular Insight Pharmaceuticals, Inc. subsidiary.

#### Item 1. Business

Progenics Pharmaceuticals develops innovative medicines for oncology. Our clinical development efforts center on late-stage oncology assets. An important focus for Progenics is targeted therapeutics and imaging agents. A number of our candidates target prostate specific membrane antigen (PSMA).

UR PRODUCT CANDID	ATES	
	In development for	Status
PSMA ADC	Treatment of prostate cancer	Phase 2 testing in chemotherapy- experienced and chemotherapy-naïve patients completed
1404	Imaging agent for prostate cancer	Phase 2 testing completed
Azedra <sup>TM</sup>	Treatment of pheochromocytoma and paraganglioma	Resumed Phase 2b registrational trial und Special Protocol Assessment (SPA)
ELISTOR ®		
Relistor-Subcutaneous injection	Treatment of opioid-induced constipation (OIC) in advanced-illness patients receiving palliative care when laxative therapy has not been sufficient	
Relistor-Subcutaneous injection	Treatment of OIC in patients with non-cancer pain	Marketed in the U.S.; licensed to Salix Pharmaceuticals; received this expanded approval from the U.S Food and Drug Administration; regulatory approval in the E.U. expected
Relistor-Oral	Treatment of OIC	Phase 3 testing completed; expect Ne Drug Application (NDA) in the U.S. to filed in 2015

## Oncology

Our principal clinical-stage product candidates in oncology are

- PSMA ADC, a fully human monoclonal antibody-drug conjugate designed to deliver a chemotherapeutic agent to cancer cells by targeting the three-dimensional structure of the PSMA protein. In a phase 2 open-label, multicenter clinical trial to assess antitumor activity, tolerability and safety, we have completed enrollment in an original cohort of chemotherapy refractory patients with metastatic castration-resistant prostate cancer (mCRPC) and a second cohort of chemotherapy-naïve patients.
- **1404** (**trofolastat**), a radio-labeled small molecule which binds PSMA and acts as an imaging agent to diagnose and detect prostate cancer, including metastases in other soft tissue and bone. We have completed a global multicentered phase 2 study assessing the diagnostic accuracy of MIP-1404 imaging in men with high-risk prostate cancer scheduled for radical prostectomy.
- Azedra, a radiotherapeutic product candidate in development as a treatment for pheochromocytoma -- rare tumors found primarily in the adrenal glands and related paraganglioma tumors occurring in other tissues that recommenced dosing patients in a resumed phase 2 trial. Azedra has Orphan Drug designation and Fast Track status in the U.S. for pheochromocytoma and paraganglioma, with clinical study conducted under a 2009 SPA with the FDA. There is currently no FDA-approved therapeutic for the treatment of pheochromocytoma.

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

We are moving forward with MIP-1095, a PSMA-targeted small molecule radiopharmaceutical, into clinical development, and plan to file an Investigational New Drug (IND) application in the U.S. Memorial Sloan-Kettering Cancer Center has agreed to serve as a study site for a phase 1 trial of this compound.

An academic institution used this compound in Germany for compassionate use in men with late stage metastatic prostate cancer who had exhausted other available therapies. This use was not in conjunction with any clinical trial. Information from this compassionate use was published in the European Journal of Nuclear Medicine and Molecular Imaging. A link to this article is found on Progenics' website.

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.

#### Relistor

Relistor, the first approved treatment for opioid-induced constipation (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, Salix 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). This was originally approved in 2008 for OIC in patients with advanced illness. In September 2014, Salix 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.

See Risk Factors.

Relistor net sales (losses) and related royalty income (loss) during the years 2012-2014 are set forth below. Salix 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 Salix of \$0.7 million. Year-to-date 2014 Relistor net sales and royalty income reported by Salix were \$20.3 million and \$3.0 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
			(i	in thousands)		
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
2012:						
Net Sales	\$ 12,300	\$ 10,800	\$	4,900	\$ 5,200 \$	33,200
Royalty Income	1,834	1,619		728	782	4,963

## **Clinical Trial Activities**

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. Following is a summary of current clinical trial activities involving our principal product candidates and Relistor.

*PSMA ADC.* In our open-label, multicenter U.S. phase 2 trial of PSMA ADC to assess anti-tumor activity and tolerability an initial cohort of chemotherapy-experienced participants with mCRPC have received initial doses of drug starting at either 2.5 mg/kg or 2.3 mg/kg; in some cases subsequent doses were adjusted based on tolerability. The study endpoints evaluate the anti-tumor effect of the compound as measured by changes in prostate specific antigen (PSA) levels, number of circulating tumor cells (CTC), pain scores, and tumor size as measured under RECIST criteria. Safety is also being assessed. Progenics has completed treatment of both the 84 patients in this chemotherapy-experienced cohort and an additional trial cohort of 35 chemotherapy-naive patients who have progressed on hormonal therapies.

Adverse events (AEs) associated with PSMA ADC observed in this phase 2 study through January 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-two 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, peripheral sensory neuropathy, pleural effusion, pneumonia primary atypical, sinus tachycardia, supraventricular tachycardia, vertigo and vomiting. Also reported were 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 were no drug-related deaths in patients treated at 2.3 mg/kg amongst the chemo-experienced cohort or the chemo-naïve cohort.

The phase 2 trial was undertaken after review and analysis of results from a phase 1 dose-ranging study of the compound in 52 mCRPC patients whose cancer had progressed despite prior treatment with taxane-based chemotherapy regimens.

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.

Through January 2015, 22% of the 171 patients treated with PSMA ADC in these trials have reported SAEs, as noted above in the descriptions of the phase 1 and phase 2 trials. In conducting these studies, Progenics has taken into account SAEs reported to date as treatment-related or possibly treatment-related; based on data currently available to it, the Company is continuing development of PSMA ADC and has not determined what effects, if any, treatment-related SAEs reported to date or that may be reported in the future may have on the development of PSMA ADC going forward. See *Risk Factors*.

1404. 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 is 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. 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 completed dosing. There have to date been no treatment related AEs reported in these studies, other than one mild injection site reaction.

Azedra. In 2006, 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 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 pheochromocytoma / paraganglioma. The primary objective of this U.S. study is 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. This phase 2 trial has enrolled 41 of the 58 patients required to be treated under the SPA, and the long-term follow up phase of the study is ongoing. To date 49% of patients receiving study drug reported SAEs, the most common of which were hematologic (12%); other SAEs included constipation, dyspnea and myelodysplastic syndrome (each at 4.5%).

This trial was suspended by Molecular Insight in late 2010 due to its lack of funding. Progenics has now resumed this trial and recommenced dosing patients.

Relistor. Salix and Progenics completed in 2011 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 average proportion of rescue-free bowel movements (RFBMs) per patient within four hours of administration over four weeks of dosing, when compared to the placebo treatment arm. 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. Salix expects to file an NDA for oral methylnaltrexone in the U.S. this year.

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.

For purposes of the foregoing summary, in general phase 1 trials are initial evaluations of safety in humans which study methods of action and metabolization; 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 dosage.

#### **Research and Development Expenses**

Research and development is essential to our business. During each of the years ended December 31, 2014, 2013 and 2012, we incurred research and development costs of \$28.6 million, \$34.6 million and \$33.0 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 - Research and Development Expenses*.

## License and Other Agreements

Following is a summary of significant agreements relating to our pipeline.

#### Oncology

Our PSMA Development Company LLC subsidiary has a collaboration agreement with Seattle Genetics, Inc. under which SGI has granted us an exclusive worldwide license to its proprietary 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 latest 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 LLC also has a worldwide exclusive licensing agreement with Abgenix (now Amgen Fremont, Inc.) to use its XenoMouse <sup>®</sup> 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.

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. The agreement contains customary representations and warranties, covenants, indemnification and other provisions.

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 research and development of product candidates, including:

- Prior to our acquisition of Molecular Insight, 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 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 \$1.2 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 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 \$0.2 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.
- A 2006 agreement with Novartis Pharma AG for exclusive rights to certain technology relating to Onalta<sup>TM</sup>, a compound which has been outlicensed to a third party which is obligated to make milestone payments and royalties consistent with Molecular's obligations under this agreement, including royalties and milestone payments, partially creditable against future royalties, totaling \$4.6 million upon the attainment of certain regulatory approvals. Either party may terminate this agreement immediately upon the occurrence of bankruptcy proceedings relating to or in the event of an uncured material breach by the other party, and Novartis may terminate in the event Molecular Insight is acquired by a direct competitor of Novartis.

#### Relistor

Under our License Agreement, Salix Pharmaceuticals is responsible for further developing and commercializing subcutaneous Relistor worldwide, including completing clinical development necessary to support regulatory marketing approvals for potential new indications and formulations, and marketing and selling the product. Salix is marketing Relistor directly through its specialty sales force in the U.S., and outside the U.S., directly through distribution and marketing partners and sublicensing regional companies. Under our Agreement with Salix, 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 Salix 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) Salix 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. The License Agreement may be terminated by either party upon an uncured material breach or specified bankruptcy events. In addition, Salix 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.

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 terminated the License Agreement, exchanged mutual releases, and the former licensee paid Progenics \$7.25 million, which has been recorded as other operating income.

Among the rights we have licensed to Salix are 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.

Clinical and Research	Numb	er of Patents	Expiration	Number of Patent Applications				
Candidates; Relistor	U.S.	International	Dates (1)	U.S.	International			
Development programs	25	84	2015-2031	13	39			
Relistor	25	165	2015-2031	21	229			
Other	0	0	-	4	8			

<sup>(1)</sup> Patent term extensions and pending patent applications may extend periods of patent protection.

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 2022 to 2026 ex-U.S. Corresponding patent applications as well as patent applications directed to methods of use (except for the U.S. patent expiring in 2023) are pending worldwide, which if issued would have expiration ranges from 2022 to 2029. We view all of these patents as significant.

Owned and in-licensed properties relating to 1404 have expiration ranges of 2022 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. Owned properties relating to MIP-1095 have expiration ranges of 2027 to 2031; we view as most significant the composition-of-matter patent on this compound, as well as radiolabeled forms, which expires in 2027. Additional U.S. patents are directed to various inventions relating to these product candidates, and corresponding patent applications are pending worldwide.

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. Salix has listed in the FDA Orange Book five U.S. patents relating to subcutaneous Relistor, which have expiration dates ranging from 2017 to 2030, and one patent (expiring in 2024) 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.

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.

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.

Underlying this process are FDA regulations relating to drug approval which are complex and multi-faceted. Two such policies which may apply to some of our current or future product candidates are "Fast Track" approval for new drugs or biologics intended for the treatment of serious or life-threatening conditions which demonstrate the potential to address unmet medical needs, and Orphan Drug designation, 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.

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 preclinical 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.

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, Salix 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 other product candidates, we engaged a third-party CMO to manufacture additional clinical trial supplies of our PSMA monoclonal antibody and we expect to continue using CMOs for other portions of the PSMA ADC manufacturing process. We have engaged third-party CMOs to manufacture API and finished drug products for clinical trial supplies of Azedra and 1404, and may in the future undertake such efforts with respect to other assets and programs. If we are unable to arrange for satisfactory CMO services, we would need to undertake such responsibilities on our own. See *Risk Factors* .

### **Sales and Marketing**

We from time to time seek strategic collaborations and other funding support for product candidates in our pipeline. We expect that we would market other products for which we obtain regulatory approval through co-marketing, co-promotion, licensing and distribution arrangements with third-party collaborators, and might also consider contracting with professional detailing and sales organizations to perform promotional and/or medical-scientific support functions for them. See *Risk Factors* .

## 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 is the first FDA-approved product for any indication involving OIC. We are, however, aware of 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<sup>TM</sup> (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. 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, which acquired Adolor Corporation in 2011, markets ENTEREG® (alvimopan) for the treatment of postoperative ileus, and is in 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. is developing 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 <sup>®</sup> (abiraterone acetate), approved in 2011 for use in combination with prednisone as a second-line (after treatment with docetaxel) advanced prostate cancer treatment, and later for use with prednisone for metastatic castration-resistant disease before the use of chemotherapy; Medivation, Inc.'s XTANDI <sup>®</sup> (enzalutamide), approved in August 2012 for patients with metastatic castration-resistant prostate cancer previously treated with docetaxel; and Bayer HealthCare Pharmaceuticals Inc.'s ALPHARADIN <sup>®</sup> (radium-223 dichloride) (marketed as XOFIGO <sup>®</sup>), submitted in late 2012 for marketing authorization for therapy of bone metastases in prostate cancer patients. A competitive product to 1404 is Jazz Pharmaceuticals' PROSTASCINT <sup>®</sup>, 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. When the disease cannot be surgically resected, patients may be treated with limited success with chemotherapy or I-131 labelled metaiodobenzylguanidine (MIBG).

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

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

## **Product Liability**

The testing, manufacturing and marketing of our product candidates and products involves an inherent risk of product liability attributable to unwanted and potentially serious health effects. To the extent we elect to test, manufacture or market product candidates and products independently, we bear the risk of product liability directly. We maintain product liability insurance coverage in the amount of \$10.0 million per occurrence, subject to a deductible and a \$10.0 million aggregate limitation. 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, 2014, we had 57 full-time employees, 11 of whom hold Ph.D. degrees and 1 of whom holds M.D. degree. At that date, 41 employees were engaged in research and development, medical, regulatory affairs and manufacturing related activities and 16 were engaged in finance, legal, administration 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

## 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 acquisition of Molecular Insight 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.

## We are dependent on Salix and other business partners to develop and commercialize Relistor, exposing us to significant risks.

We rely on Salix to complete development and obtain regulatory approvals for additional formulations of and indications for Relistor worldwide. We are and will be dependent upon Salix 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 Salix and its sublicensees, which have significant discretion in determining the efforts and resources they apply to sales of Relistor. Salix 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 Salix and other partners may not be scientifically, clinically or commercially successful. For example, Salix has a variety of marketed products. Salix is not, however, a large diversified pharmaceutical company and does not have resources commensurate with such companies. Salix has 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. Changes of this nature might also occur if Salix were acquired or if its management changed, such as the departure of Salix's chief financial officer in November 2014 and its chief executive officer in January 2015. We may have future disagreements with Salix, 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 Salix concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property.

Furthermore, Salix disclosed on November 6, 2014 that its Audit Committee has retained outside counsel and is conducting a review of issues related to its management's prior characterizations of wholesaler inventory levels; that it has notified the SEC that its Audit Committee is conducting this review; and made other management- and operations-related disclosures. On January 28, 2015, Salix disclosed that Salix's previously issued audited consolidated financial statements for the year ended December 31, 2013 and the previously issued unaudited consolidated financial statements for the fiscal quarters ended March 31, June 30, and September 30, 2014, and the disclosures and related communications for each of those periods, require correction of certain errors and should no longer be relied upon.

Salix recently agreed to enter into a merger agreement with Valeant Pharmaceuticals International to acquire all of its outstanding common stock. The merger of Salix and Valeant may negatively affect our collaborative agreements with Salix and could have a material adverse effect on our business.

In March 2015, Salix and Valeant agreed to enter into a merger agreement. We cannot predict how a combined Salix and Valeant may view the utility and attractiveness of Relistor, or if any other potential bidders for Salix may come forward. Upon completion of this transaction or for other reasons, a combined Salix and Valeant may change its strategic focus or pursue alternative products in a manner that results in a termination of, or reduction in, revenues to us. We cannot predict whether a combined Salix and Valeant will determine to continue, seek to change or terminate our collaboration on Relistor, or devote the same resources Salix currently dedicates to it. If a combined Salix and Valeant were to terminate the collaboration, we would no longer receive milestone and royalty payments and would need to undertake development and commercialization of Relistor ourselves or through another collaboration or licensing arrangement. We may not learn of their plans for Relistor and our collaboration unless and until the proposed transaction closes. Any decision by Salix and Valeant or any other potential third-party bidder not to proceed or perform under our existing agreements could have a material adverse effect on our business.

### The Relistor program continues to be subject to risk.

Future developments in the commercialization of Relistor may result in Salix 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.

Salix has previously disclosed in regulatory filings that additional information and additional guidance from the FDA could result in the termination of its oral OIC 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.

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.

For example, as described in *Business – Clinical Trial Activities*, in the phase 2 trial of one of our principal product candidates, PSMA ADC, investigators have reported SAEs including two deaths, in the 2.5 mg/kg dosing group. Based on data currently available to us, the Company is continuing development of PSMA ADC, at 2.3 mg/kg dose, and has not determined what effects, if any, treatment-related SAEs reported to date or that may be reported in the future may have on the development of PSMA ADC going forward. If, however, we, together with or independently of investigators participating in our clinical trials, or regulators evaluating PSMA ADC were to determine that this candidate cannot safely be administered to patients with sufficient therapeutic effect, we may determine to attempt to reformulate or otherwise change the candidate and/or its administration to alleviate such concerns, which could result in costs and delays that could impair the value of the candidate. If such costs and delays were sufficiently large, we could determine to abandon the PSMA ADC program. Concerns about the safety and/or efficacy of PSMA ADC could also make it more difficult or impossible for us to enter into licensing, collaboration or other arrangements with third parties for further development and commercialization of PSMA ADC. Any of these possibilities could have material adverse effects on Progenics' business, its financial condition, and/or the price of our stock.

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 other product candidates, 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 Salix, we are dependent on Salix for compliance with these regulatory requirements as they apply to Relistor. Salix has 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 Salix's financial condition or results of operations.

## 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 PSMA ADC program) 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.

## 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 Salix'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.

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

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 in addition to the dilution experienced as a result of our recent equity offerings and the 2013 Molecular Insight acquisition, 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 the Company's 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.

## If we are unable to negotiate 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.

## 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. Preclinical 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.

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. We, our collaborators or regulators may also amend, suspend or terminate clinical trials if we or they believe that the participating subjects 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.

If the results of any future Relistor trials are not satisfactory or we or our collaborators encounter problems enrolling subjects, 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 trials of PSMA ADC and 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, Salix 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.

## Our product candidates may not obtain regulatory approvals needed for marketing.

None of our product candidates, other than Relistor for the treatment of OIC in patients with advanced illnesses and for those with chronic, non-cancer pain, has been approved by applicable regulatory authorities for marketing. 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.

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

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors 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 the timing of regulatory approvals, product launches and reimbursement programs for existing and expanded uses or generic, over-the-counter or other competitors; price increases for the product and relative prices of competing products; product development efforts for new indications; availability of 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 payors 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 payors 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 some 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.

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.

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.

Salix 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 not result in the supply of sufficient 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 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 Salix, Salix 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. If we were to decide to establish a commercial-scale manufacturing facility in the future, we would require substantial additional funds and be required to hire and train significant numbers of employees and comply with applicable regulations.

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

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

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

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

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

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 2022 to 2026 ex-U.S. Corresponding patent applications as well as patent applications directed to methods of use (except for the U.S. patent expiring in 2023) are pending worldwide, which if issued would have expiration ranges from 2022 to 2029. We view all of these patents as significant.

Owned and in-licensed properties relating to the 1404 product candidate have expiration ranges of 2023 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. Additional U.S. patents are directed to various inventions relating to the product candidate, and corresponding patent applications are pending worldwide.

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. Salix has listed in the FDA Orange Book five U.S. patents relating to subcutaneous Relistor, which have expiration dates ranging from 2017 to 2030, and one patent (expiring in 2024) 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 Seattle Genetics, Inc. 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.

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.

#### 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 Salix 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.

## 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 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 Salix, we are responsible for product liability claims arising out of clinical trials that were conducted under our supervision. We are indemnified by Salix under our license agreement with Salix for product liability exposure arising from its supply, marketing and sales of Relistor, and maintain our own product liability insurance coverage in the amount of \$10.0 million per occurrence, subject to a deductible and a \$10.0 million 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.

## 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.

## Heath 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 payors 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 payors 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 payors 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 payors 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.

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

#### 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 2013 and 2012 and while we reported operating income for 2014, as a result of a milestone payment from Salix, 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.

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

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

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

Our stock price has a history of significant volatility. It has varied between a high of \$7.62 and a low of \$3.10 in 2014 and between a high of \$6.47 and a low of \$2.53 in 2013. 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 have an adverse effect on our ability to raise capital and may adversely affect the market price of our common stock.

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

At 2014 year-end, our directors and executive officers together beneficially owned or controlled approximately 6 percent of our outstanding common shares, including shares currently issuable upon option exercises, and our five largest other stockholders approximately 53.5 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 exercisability 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, 2014.

## **Item 2. Properties**

At December 31, 2014, we occupied approximately 72,900 square feet of laboratory and office space in Tarrytown, New York, pursuant to lease agreements expiring in December 2020 under which we pay rent and facilities charges including utilities, taxes and operating expenses. We believe our existing facilities are adequate to meet our present requirements.

## **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 the Company 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. The Company believes the former employee's claims are without merit and is contesting the matter vigorously. The federal District Court hearing the case issued in July 2013 an order denying our motion for summary judgment dismissing the former employee's complaint, making it likely that the proceeding will continue to trial. Given the uncertainty attendant to the proceeding, we have accrued amounts in connection with this matter which are not material to these Consolidated Financial Statements.

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 terminated the License Agreement, exchanged mutual releases, and the former licensee paid Progenics \$7.25 million, which has been recorded as other operating income.

## **Item 4. Not Applicable**

#### PART II

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

## **Price Range of Common Stock**

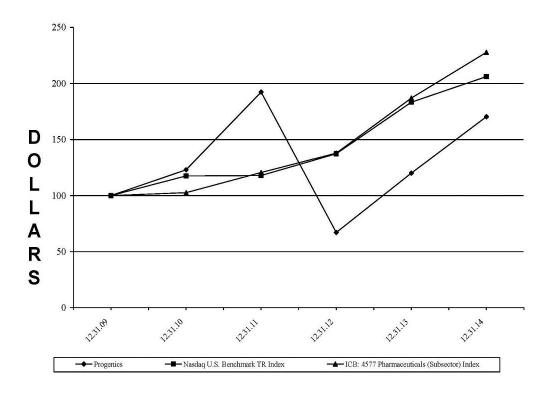
Our common stock is quoted on The NASDAQ Stock Market LLC under the symbol PGNX. The following table sets forth, for the periods indicated, the high and low sales price per share of the common stock, as reported on NASDAO.

		High	Low	
2014:	Fourth quarter	\$ 7.62	\$ 4.2	6
	Third quarter	5.72	4.0	2
	Second quarter	4.65	3.1	0
	First quarter	7.45	3.7	5
	•			
2013:	Fourth quarter	\$ 5.90	\$ 3.4	.5
	Third quarter	6.47	4.3	6
	Second quarter	5.57	3.5	4
	First quarter	5.96	2.5	3

On March 10, 2015, the last sale price for our common stock, as reported by The NASDAQ Stock Market LLC, was \$6.66. There were approximately 70 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, 2009.



## **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, 2014 and 2013 and for each of the three years in the period ended December 31, 2014 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, 2012, 2011 and 2010 and for each of the two years in the period ended December 31, 2011 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,

		2014		2013		2012		2011		2010
Consolidated Statement of Operations Data:				(in thousands, except per share			data)			
Revenues:										
Collaboration revenue	\$	41,196	\$	1,595	\$	8,525	\$	76,764	\$	1,413
Royalty income		3,101		5,923		4,963		3,046		1,826
Research grants		-		275		488		4,810		4,573
Other revenues		80		69		72		176		140
Total revenues		44,377		7,862		14,048		84,796		7,952
Expenses:										
Research and development		27,737		33,391		31,332		52,555		50,151
License fees - research and development		498		567		1,170		578		1,270
Royalty expense		357		624		499		405		241
General and administrative		14,944		14,602		15,214		18,876		23,321
Depreciation and amortization		545		939		1,324		2,066		2,853
Intangible impairment charges		2,676		919		-		-		_
Change in contingent consideration liability		1,500		(200)		-		-		-
Total expenses		48,257		50,842		49,539		74,480		77,836
Other operating income		7,250		-		-		-		-
Operating income (loss)		3,370	_	(42,980)	_	(35,491)		10,316		(69,884
Other income:	_	3,370		(12,500)	_	(33,131)	_	10,510	_	(0),001
Interest income		51		46		60		65		64
		51	_	46			-	65	_	
Total other income		31	_	40		60		03		64
Net income (loss) before provision for income taxes		3,421		(42,934)		(35,431)		10,381		(69,820
Income tax benefit		989		362		-		-		95
Net income (loss)	\$	4,410	\$	(42,572)	\$	(35,431)	\$	10,381	\$	(69,725
Per share amounts on net income (loss):										
Basic	\$	0.06	\$	(0.76)	\$	(1.02)	\$	0.31	\$	(2.14
Diluted	\$	0.06	\$	(0.76)	\$	(1.02)	\$	0.31	\$	(2.14
					ī	December 31,				
		2014		2013		2012		2011		2010
					(i	in thousands)				
Consolidated Balance Sheet Data:	\$	119,302	Φ	65,860	Φ	58,838	\$	70,105	Ф	47,918
Cash and cash equivalents	Ф	119,302	\$		\$		Ф		\$	
Auction rate securities		115 241		2,208		3,240		3,332		3,608
Working capital		115,241		64,055		58,805		65,890		42,207
Total assets		161,037		114,541		76,308		80,110		62,738
Deferred revenue - current		-		-		838		204		-
Deferred revenue - long term		29,443		29.02 <i>5</i>		1.079		162		1 625
Other liabilities - long term				28,935		1,078		1,497		1,635
Total stockholders' equity		124,909		78,979		66,568		71,801		51,308
			2	27						

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

## Overview

*General*. As discussed in *Business*, above, we have completed phase 2 clinical trials of two product candidates for prostate cancer, and resumed a pivotal phase 2 trial of an ultra-orphan radiotherapy candidate for pheochromocytoma. We are moving forward with MIP-1095, a compound originally developed by Molecular Insight, into clinical development, and expect to file an IND application in the U.S. this year.

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 Salix 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, commercialization milestone and revenue-sharing payments from Salix's Relistor operations. Royalty and milestone payments from Relistor depend on success in development and commercialization, which is dependent on many factors, such as Salix'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 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 has been recorded as other operating income.

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 2014, expenses for Oncology, primarily related to PSMA ADC, 1404, AZEDRA<sup>TM</sup> and 1095, were \$27.3 million compared to \$32.9 million in 2013 and \$28.6 million in 2012. Expenses for Relistor and other programs in 2014 were \$1.3 million, compared to \$1.7 million in 2013 and \$4.4 million in 2012. We expect to incur operating losses for the foreseeable future. At December 31, 2014, we held \$119.3 million in cash and cash equivalents, an increase of \$53.4 million from \$65.9 million at 2013 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 other 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 and 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. Salix 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 Salix, we received a development milestone of \$40 million upon U.S. marketing approval for subcutaneous Relistor in non-cancer pain patients 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 Salix 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) Salix 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).

Salix has secured distribution for Relistor in the European territory, licensed Link Medical Products Pty Limited for distribution in Australia, New Zealand, South Africa and certain other markets in Asia, and in the third quarter entered into an agreement with Lupin Limited for distribution of Relistor in Canada.

### Results of Operations (amounts in thousands unless otherwise noted)

	2014		2013			2012	2014 vs. 2013	2013 vs. 2012
							Percent	Change
Revenues	\$	44,377	\$	7,862	\$	14,048	464%	(44%)
Expenses	Ψ	(48,257)	Ψ	(50,842)	Ψ	(49,539)	(5%)	, ,
Other operating income		7,250					100%	N/A
Operating income (loss)		3,370		(42,980)		(35,491)	(108%)	21%
Other income		51		46		60	11%	(23%)
Income tax benefit		989		362		=	173%	100%
Net income (loss)	\$	4,410	\$	(42,572)	\$	(35,431)	(110%)	20%

#### **Revenues** (amounts in thousands unless otherwise noted):

Sources of revenue during the years indicated below included license and other agreements with Salix 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	2014		2013		2012	2014 vs. 2013	2013 vs. 2012
						Percent (	Change
Collaboration revenue	\$	41,196	\$ 1,595	\$	8,525	2,483%	(81%)
Royalty income		3,101	5,923		4,963	(48%)	19%
Research grants		-	275		488	(100%)	(44%)
Other revenues		80	69		72	16%	(4%)
Total	\$	44,377	\$ 7,862	\$	14,048	464%	(44%)

**Collaboration revenue.** During 2014, we recognized revenue from milestone partnering arrangements, primarily resulting from the \$40,000 milestone from Salix, 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.

During 2012, we recognized revenue from upfront and reimbursement payments from partnering arrangements consisting of (i) \$7,949 from PRO 140 and *C. difficile* partnering, and (ii) \$558 from Salix. As of December 31, 2012, \$838 is recorded in deferred revenue – current.

During 2014, 2013 and 2012, we recognized \$2, \$15 and \$18, respectively, of reimbursement revenue for activities requested by former collaborators.

**Royalty income.** During the periods presented below we recognized royalty income primarily based on the below net sales of Relistor reported by Salix.

	 Relistor Net Sales										
	Years Ended December 31,										
	2014		2013		2012						
U.S.	\$ 16,200	\$	35,000	\$	29,200						
Ex-U.S.	 4,100		4,400		4,000						
Global	\$ 20,300	\$	39,400	\$	33,200						

Salix 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 Salix of \$0.7 million.

**Research grants.** During the last three years, we recognized \$0, \$275 and \$488, respectively, as revenue from federal government grants from the NIH to support research and development programs. Decreases in grant revenue primarily resulted from lower reimbursable expenses year-to-year. 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.

## **Expenses (amounts in thousands unless otherwise noted):**

**Research and Development Expenses** include scientific labor, clinical trial costs, supplies, product manufacturing costs, consulting, license fees, royalty payments and other operating expenses. Research and development expenses decreased to \$28,592 for 2014 from \$34,582 for 2013 and from \$33,001 for 2012. See *Liquidity and Capital Resources – Uses of Cash*, for details of the changes in these expenses by project. Portions of our expenses during 2013 and 2012 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:

	:	2014	 2013	2	2012	2014 vs. 2013	2013 vs. 2012
						Percent	change
Salaries and benefits	\$	9,003	\$ 12,481	\$	15,372	(28%	(19%)

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.

2013 vs. 2012 Salaries and benefits decreased primarily due to a decline in average headcount, and reflecting a non-recurring retirement expense of \$1,804 incurred in the first quarter of 2012.

	 2014	2013	2012	2014 vs. 2013	2013 vs. 20	)12
	 			Percer	nt change	
Share-based compensation	\$ 1,843	\$ 2,012	\$ 4,060	(89	<b>%</b> )	(50%)

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

2013 vs. 2012 Share-based compensation decreased primarily due to lower equity incentives expenses, and reflecting non-recurring 2012 retirement-related option and restricted stock expense of \$1,638.

	 2014	 2013	 2012	2014 vs. 2013	2013 vs. 2012
	 			Percent	change
Clinical trial costs	\$ 6,510	\$ 8,862	\$ 2,692	(27%	) 229%

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.

2013 vs. 2012 Clinical trial costs increased primarily due to higher expenses for Oncology (\$6,214), primarily related to 1404 and PSMA ADC, partially offset by lower expenses for Relistor and other programs (\$44).

	2(	)14	 2013	 2012	2014 vs. 2013	2013 vs. 2012
Laboratory and manufacturing supplies and					Percent	change
equipment	\$	193	\$ 632	\$ 592	(69%)	7%

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

2013 vs. 2012 Laboratory and manufacturing supplies and equipment increased by \$511 for other programs, including second quarter impairment losses from the write-off of laboratory equipment in connection with an amendment to the Company's Tarrytown lease, partially offset by lower Oncology expenses (\$471), primarily from a decline in lab supplies for PSMA ADC.

	 2014	 2013	 2012	2014 vs. 2013	2013 vs. 20	12
Contract manufacturing and	 			Percen	t change	
subcontractors	\$ 5,191	\$ 2,042	\$ 3,111	154%	<b>6</b>	(34%)

2014 vs. 2013 Contract manufacturing and subcontractors 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.

2013 vs. 2012 Contract manufacturing and subcontractors decreased, primarily due to lower expenses for Oncology (\$571) and Relistor and other programs (\$498).

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

		2014		2013		2012	2014 vs. 2013 2013 v		s. 2012
	_					_	Percei	nt change	
Consultants	\$	887	\$	905	\$	330	$(2^{\circ}$	<b>%</b> )	174%

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).

2013 vs. 2012 Consultants expense increased primarily due to higher expenses for Oncology (\$613), partially offset by lower expenses for Relistor and other programs (\$38).

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.

	2	2014		2013	2012	2014 vs. 2013	2013 vs. 2012
						Perce	nt change
License fees	\$	498	\$	567	\$ 1,170	(12)	<b>%</b> ) (52%)

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.

2013 vs. 2012 License fees decreased due to lower expenses for Oncology (\$573) and Relistor and other programs (\$30).

	 2014	 2013	 2012	2014 vs. 2013	2013 vs. 2012
				Percent	change
Royalty expense	\$ 357	\$ 624	\$ 499	(43%	25%

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

2013 vs. 2012 The increase in royalty expense was primarily due to higher net sales of Relistor in 2013.

	2014	2013	2012	2014 vs. 2013	2013 vs. 201	2
				Percer	t change	
Other operating expenses	\$ 4,110	\$ 6,457	\$ 5,175	(36%	<b>6</b> ) 2	25%

2014 vs. 2013 Other operating expenses decreased from 2013 primarily due to lower expenses for rent (\$1,837), other operating expenses (\$292), facilities (\$164), insurance (\$27) and travel (\$27).

2013 vs. 2012 Other operating expenses increased from 2012 primarily due to increases in rent (\$1,131), as a result of lease amendment and termination expenses, travel (\$106), other operating expenses (\$140) and insurance (\$57), partially offset by a decrease in facilities (\$152).

**General and Administrative Expenses** increased to \$14,944 for 2014 from \$14,602 for 2013 and decreased from \$15,214 for 2012, as follows:

	2014		2013		2012	2014 vs. 2013 2013 vs. 2012		
						Percen	t change	
Salaries and benefits	\$ 4,398	\$	4,821	\$	6,493	(9%	(26%)	<b>o</b> )

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

2013 vs. 2012 Salaries and benefits decreased primarily due to 2012 accrued severance expense resulting from headcount reductions, while the average headcount remained unchanged.

	 2014	2013	 2012	2014 vs. 2013	2013 vs. 2012	_
	 			Percent	t change	
Share-based compensation	\$ 1,680	\$ 1,534	\$ 2,476	10%	6 (38	<b>3%</b> )

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

2013 vs. 2012 Share-based compensation decreased primarily due to lower equity incentives expenses, which included restructuring expenses in 2012.

	 2014		2013		2012	2014 vs. 2013	2013 vs. 2012
						Percent	change
Consulting and professional fees	\$ 5,060	\$	3,922	\$	2,362	29%	66%

2014 vs. 2013 Consulting 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).

2013 vs. 2012 Consulting and professional fees increased due to higher consulting (\$697), patent (\$457), legal (\$256), audit (\$101) and other fees (\$49).

	 2014	 2013	 2012	2014 vs. 2013	2013 vs. 2012
				Percent o	change
Other operating expenses	\$ 3,806	\$ 4,325	\$ 3,883	(12%)	11%

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).

2013 vs. 2012 Other operating expenses increased due to higher expenses for market research (\$158), recruiting (\$112), investor relations (\$109) and taxes (\$108) and other operating expenses (\$127), partially offset by a decrease in rent (\$172).

Depreciation and Amortization Expenses decreased from 2013 to 2014 and from 2012 to 2013, as follows:

	2014		2013		2012		2014 vs. 2013	2013 vs. 201	2
							Percer	nt change	
Depreciation and amortization	\$	545	\$	939	\$	1,324	(42%	<b>(2</b> )	29%)

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

2013 vs. 2012 Depreciation and amortization expense decreased primarily due to lower leasehold improvements and machinery and equipment fixed asset balances.

Intangible Impairment Charges increased from 2013 to 2014 and from 2012 to 2013, as follows:

	2014	 2013	20	12	2014 vs. 2013	2013 vs. 2012
					Percent	change
Intangible impairment charges (non-cash)	\$ 2,676	\$ 919	\$	-	191%	100%

2014 vs. 2013 As of December 31, 2014 indefinite-lived intangible assets decreased by \$2,679, from \$31,379 million to \$28,700 million, 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.

2013 vs. 2012 As of December 31, 2013 indefinite-lived intangible assets decreased by \$919, from \$32,298 million to \$31,379 million, resulting from our annual impairment testing, with the corresponding impairment charges recorded 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.

Change in Contingent Consideration Liability increased from 2013 to 2014 and decreased from 2012 to 2013, as follows:

	 2014		2013		2012	2014 vs. 2013	2013 vs. 2012
						Percei	nt change
Change in contingent consideration liability (non-cash)	\$ 1,500	\$	(200)	\$	-	(8509	<b>(100%)</b>

2014 vs. 2013 The review of the contingent consideration liability fair value resulted in \$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.

2013 vs. 2012 The fourth quarter of 2013 review of the contingent consideration liability fair value resulted in a \$200 decrease, from \$15,900 to \$15,700, which has been recorded as non-cash expense in the Consolidated Statements of Operations. The decrease in contingent consideration liability was primarily due to an increase in the discount period.

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):

	 2014	2013	 2012	2014 vs. 2013	2013 vs. 2012
			 	Percent	change
Other operating income	\$ 7,250	\$ -	\$ -	100%	N/A

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):

	 2014		2013		2012	2014 vs. 2013	2013 v	rs. 2012
						Percen	t change	
Interest income	\$ 51	\$	46	\$	60	119	<b>%</b>	(23%)

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.

2013 vs. 2012 Interest income decreased primarily due to lower average interest rates in 2013 than in 2012, partially offset by increases resulting from higher average balances of cash equivalents.

Interest income, as reported, is primarily the result of investment income from auction rate securities.

# Income Taxes (amounts in thousands unless otherwise noted):

For the year ended December 31, 2014, our book income was \$4,410, resulting primarily from \$40,000 in milestone revenue from Salix 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. For 2014 and 2013, income tax benefit of \$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 2012 there was no provision for income taxes due to pre-tax loss.

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

Our 2014 net income was \$4,410, compared to net losses of \$42,572 for 2013 and \$35,431 for 2012.

#### 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, collaborations, grants and contracts, royalties, interest on investments, and proceeds from the exercise of outstanding options and warrants.

In 2014, we have 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 and 2012, we received a \$5,000 upfront payment from partnering of the *C. difficile* program and a \$3,500 payment upon sale of our PRO 140 program, respectively. 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, 2014, we held \$119,302 in cash and cash equivalents, an increase of \$53,442 from \$65,860 at December 31, 2013. 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 were redeemed at par in the fourth quarter of 2014.

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 provided by operating activities was \$13,726 for 2014, 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. Cash used in operating activities for 2013 and 2012 was \$36,107 and \$34,644, respectively, due to excess of expenditures on our research and development programs and general and administrative costs over cash received from collaborators and government grants. 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. In December 2012, we completed a public offering of 12.7 million shares of common stock for net proceeds of approximately \$23,348.

#### Sources of Cash (amounts in thousands unless otherwise noted)

*Operating Activities.* In addition to the settlement payment received from Ono 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. During 2012 we received \$9,393 under collaborations, out-licenses and sale of assets, consisting of (i) \$404 in reimbursement payments under the Salix License Agreement, (ii) \$5,461 in royalties from Salix, (iii) \$3,500 from the sale of our PRO 140 program and (iv) \$28 under another out-license.

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. For 2013 and 2012, we received \$287 and \$576, respectively, of revenue from all of our NIH awards.

Changes in Accounts receivable and Accounts payable for 2014, 2013 and 2012 resulted from the timing of receipts from Salix, 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.* Approximately 95% of our \$119,302 in cash and cash equivalents at December 31, 2014 was invested in money market funds.

*Financing Activities.* During 2014, net cash provided by financing activities included \$37,459 in net proceeds from the issuance of 8,750 shares of common stock. In addition, during 2014, 2013 and 2012, we received cash of \$428, \$71 and \$306, respectively, from exercise of stock options and sales of common stock in satisfaction of severance obligations (in 2012). 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 pre-clinical studies and clinical trials, pursuing regulatory approvals for product candidates, filing and prosecuting patent applications and defending patent claims. Included in the 2012 period presented below is \$2,073 of cash disbursements incurred in connection with a former senior executive first quarter retirement. 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.

Research and development costs incurred by project over the past three years were as follows:

	2014			2013	2012
			(in	millions)	
Oncology	\$	27.3	\$	32.9	\$ 28.6
Relistor and other programs		1.3		1.7	4.4
Total	\$	28.6	\$	34.6	\$ 33.0

We will require additional funding to continue our research and product development programs, conduct pre-clinical studies and 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 product in-licensing and any possible acquisitions.

Investing Activities. During the past three years, we have spent \$714, \$137 and \$767, respectively, on capital expenditures.

# **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, 2014 for future payments under these agreements:

		Payments due by Period									
	Total		ess than ne year		3 years millions)	3 t	o 5 years	Gı	reater than 5 years		
Operating leases	\$ 12.1	\$	1.9	\$	3.9	\$	4.1	\$	2.2		
License, collaboration and other											
agreements:											
Fixed payments	1.0		0.3		0.4		0.3		-		
Contingent payments (1)	 104.6				2.3		16.9		85.4		
Total	\$ 117.7	\$	2.2	\$	6.6	\$	21.3	\$	87.6		

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

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.

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 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.

Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term deferred revenue. The classification of deferred revenue as short-term or long-term is based upon the periods in which we expect to perform our collaboration arrangement obligations including non-reimbursable technical assistance.

*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.

For performance stock option awards to our CEO (awarded in 2012 and 2011 only), vesting occurs upon achievement of specified performance-based milestones. The awards, which have an exercise price equal to the closing price of our common stock on the date of grant, are valued using the Black-Scholes option pricing model: the expense related to these grants is recognized during the period, if any, in which each performance milestone is achieved.

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 to 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 the fourth quarter of 2014, all of the \$2.2 million (net of \$0.2 million unrealized loss) auction rate securities remaining at December 31, 2013 have been redeemed at par. Our available-for-sale investment portfolio consists of money market funds and, prior to the fourth quarter redemption at par, \$2.4 million face amount of auction rate securities (ARS), and is recorded at fair value in the accompanying Consolidated Balance Sheets in accordance with ASC 320 Investments – Debt and Equity Securities. The change in the fair value of these investments is recorded as a component of other comprehensive income (loss). We expect to recover the amortized cost of all of our investments at maturity.

*In-Process Research and Development and Goodwill.* In connection with the acquisition of Molecular Insight, we have established a policy for accounting for intangible assets, under which in process research and development (IPR&D) and goodwill are initially measured at fair value and capitalized as an intangible asset and an impairment test for these intangibles is performed annually in the fourth quarter, unless impairment indicators require an earlier evaluation. Upon and subject to commercialization of these candidates, the IPR&D will be 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 were variable and totaled \$112.8 million at December 31, 2014. As a result, we do not believe that these investment balances have a material exposure to interest-rate risk.

#### **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 Principal Financial Officer (PFO), 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 PFO, 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 PFO 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, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and PFO 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, 2014. 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, 2014 as stated in their report which is provided below.

# 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, 2014, 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.

In our opinion, Progenics Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, 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, 2014 and 2013 and the related consolidated statements of operation, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014 of Progenics Pharmaceuticals, Inc. and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut March 16, 2015

# Item 9B. Other Information

None.

# **PART III**

The information required by the Form 10-K Items listed in the following table will be included under the respective headings specified for such Items in our definitive proxy statement for our 2015 Annual Meeting of Stockholders to be filed with the SEC:

Item of Form 10-K **Location in 2015 Proxy Statement Directors, Executive Officers and Corporate** Item 10. Election of Directors. Governance 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. Security Ownership of Certain Beneficial Owners Equity Compensation Plan Information. Item 12. and Management and Related Stockholder Matters Security Ownership of Certain Beneficial Owners and Management. **Item 13.** Certain Relationships and Related Transactions, Certain Relationships and Related Transactions. and Director Independence Affirmative Determinations Regarding Director Independence and Other Matters.

Item 14. Principal Accounting Fees and Services

Fees Billed for Services Rendered by our Independent Registered Public Accounting Firm.

Pre-approval of Audit and Non-Audit Services by the Audit Committee.

# **PART IV**

# Item 15. Exhibits, Financial Statement Schedules

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

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

Consolidated Financial Statements of Progenics Pharmaceuticals, Inc.:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2014 and 2013

Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012

Notes to Consolidated Financial Statements

(b) 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.

(c) 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.

# 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, 2014 and 2013 and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. Our audits also included the financial statement schedule listed in the Index at Item 15(b). 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, 2014 and 2013 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, 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 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP Hartford, Connecticut March 16, 2015

# CONSOLIDATED BALANCE SHEETS (amounts in thousands, except for par value and share amounts)

	December 31,			31,
		2014		2013
Assets				
Current assets:				
Cash and cash equivalents	\$	119,302	\$	65,860
Accounts receivable, net		109		2,879
Other current assets		2,515		1,943
Total current assets		121,926		70,682
Auction rate securities		-		2,208
Fixed assets, at cost, net of accumulated depreciation and amortization		2,552		2,413
Intangible assets, net (Note 2)		28,700		31,379
Goodwill		7,702		7,702
Other assets		157		157
Total assets	\$	161,037	\$	114,541
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	6,570	\$	6,512
Other current liabilities		115		115
Total current liabilities		6,685		6,627
Contingent consideration liability		17,200		15,700
Deferred tax liability - long term		11,332		12,321
Other liabilities		911		914
Total liabilities		36,128		35,562
Commitments and contingencies (Note 9)				
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 2014 and 2013; issued –				
69,832,949 in 2014 and 61,025,404 in 2013		91		79
Additional paid-in capital		589,826		548,510
Accumulated deficit		(462,267)		(466,677)
Accumulated other comprehensive loss		-		(192)
Treasury stock, at cost (200,000 shares in 2014 and 2013)		(2,741)		(2,741)
Total stockholders' equity		124,909		78,979
Total liabilities and stockholders' equity	\$	161,037	\$	114,541

# **CONSOLIDATED STATEMENTS OF OPERATIONS** (amounts in thousands, except net income (loss) per share)

Years Ended December 31. 2014 2012 2013 Revenues: Collaboration revenue 41.196 1.595 \$ 8,525 Royalty income 3,101 5,923 4,963 Research grants 488 80 Other revenues 69 72 Total revenues 44,377 7,862 14,048 Expenses: Research and development 27,737 33,391 31,332 License fees – research and development 498 567 1,170 Royalty expense 357 624 499 General and administrative 14,944 14,602 15,214 Depreciation and amortization 939 545 1,324 Intangible impariment charges 919 2,676 Change in contingent consideration liability 1,500 (200)Total expenses 48,257 50,842 49,539 Other operating income 7,250 Operating income (loss) (42,980)3,370 (35,491)Other income: Interest income 60 51 46 Total other income 51 46 60 3,421 (42,934)(35,431)Net income (loss) before income tax benefit Income tax benefit 989 362 Net income (loss) 4,410 (42,572)(35,431)Net income (loss) per share - basic 0.06 (0.76)(1.02)Weighted-average shares - basic 68,185 55,798 34,754 Net income (loss) per share - diluted 0.06 (0.76)(1.02)Weighted-average shares - diluted 68,243 55,798 34,754

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (amounts in thousands)

	Years Ended December 31,							
	2014		2013		2012			
Net income (loss)	\$ 4,410	\$	(42,572)	\$	(35,431)			
Other comprehensive income:								
Net change in unrealized loss on auction rate securities	 192		68		8			
Total other comprehensive income	 192		68		8			
Comprehensive income (loss)	\$ 4,602	\$	(42,504)	\$	(35,423)			

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY For the Years Ended December 31, 2014, 2013 and 2012 (amounts in thousands)

	Common	Stock	Additional Accumulated		Accumulated Other	Treasury	Stock			
	Shares	Amount	Paid-In Capital	Deficit	Comprehensive Income (Loss)	Shares	Amount	Total		
Balance at December 31, 2011	34,046	44	463,440	(388,674)	(268)	(200)	(2,741)	71,801		
Net loss	-	-	-	(35,431)	-	_	-	(35,431)		
Other comprehensive income	-	-	-	` · · · · ·	8	-	-	8		
Compensation expenses for share-based payment arrangements	-	-	6,536	-	-	-	-	6,536		
Sale of common stock in public offering, net of underwriting discounts and commissions (\$1,518) and offering expenses (\$434)	12,650	17	23,331	-	<u>-</u>	_	<u>-</u>	23,348		
Forfeitures of restricted stock	(6)	-	-	-	-	-	-	-		
Sale of common stock under stock										
incentive plan and exercise of stock										
options	75	_	306				<u> </u>	306		
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	- ,		40,000	-	-	-	-	40,078		
Exercise of stock options	(1) 14	-	71	-	-	-	-	71		
Balance at December 31, 2013										
Net income	61,025	79	548,510	(466,677)	(192)	(200)	(2,741)	78,979		
Other comprehensive income	-	-	-	4,410	-	-	-	4,410		
Compensation expenses for share-based	-	-	-	-	192	-	-	192		
payment arrangements			3,523					3,523		
Sale of common stock in public offering,	-	-	3,323	-	-	-	-	3,323		
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				<u> </u>	428		
Balance at December 31, 2014	69,833	91	589,826	(462,267)		(200)	(2,741)	124,909		

# CONSOLIDATED STATEMENTS OF CASH FLOWS (amounts in thousands)

				led December	· 31,	
		2014		2013	Í	2012
Cash flows from operating activities:						
Net (loss) income	\$	4,410	\$	(42,572)	\$	(35,431)
Adjustments to reconcile net income (loss) to net cash provided by (used in)						
operating activities:						
Depreciation and amortization		545		939		1,324
(Gains) losses on sales of fixed assets		(110)		204		(327)
Intangible impairment charge		2,676		919		-
Deferred income tax		(989)		(362)		-
Change in contingent consideration liability		1,500		(200)		-
Expenses for share-based compensation awards		3,523		3,546		6,536
Acquisition of subsidiary escrow shares returned		(82)		-		-
Changes in assets and liabilities:						
Decrease (increase) in accounts receivable		2,770		4,114		(5,421)
(Increase) decrease in other current assets		(572)		336		(754)
Decrease (increase) in deferred tax and other assets		-		2,044		(2,002)
Increase (decrease) in accounts payable and accrued expenses		58		(1,956)		(691)
(Decrease) increase in deferred revenue – current		-		(886)		634
(Decrease) increase in deferred tax and other current liabilities		-		(2,069)		2,069
(Decrease) in deferred revenue - long term		-		-		(162)
(Decrease) in other liabilities		(3)		(164)		(419)
Net cash provided by (used in) operating activities		13,726		(36,107)		(34,644)
Cash flows from investing activities:						
Cash acquired in acquisition of subsidiary		-		1,888		-
Capital expenditures		(714)		(137)		(767)
Proceeds from sales of fixed assets		143		174		390
Proceeds from redemption of auction rate securities		2,400		1,100		100
Net cash provided by (used in) investing activities		1,829		3,025		(277)
Cash flows from financing activities:						
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		23,348
Proceeds from the exercise of stock options and sale of common stock under the						
employee stock purchase plans		428		71		306
Net cash provided by financing activities		37,887		40,104		23,654
Net increase (decrease) in cash and cash equivalents		53,442		7,022		(11,267)
Cash and cash equivalents at beginning of period		65,860		58,838		70,105
Cash and cash equivalents at end of period	\$	119,302	\$	65,860	\$	58,838
2 cust equi equi aleme al period	<del>*</del>	-17,002	<u>Ψ</u>	32,000	<u> </u>	23,330
Supplemental disclosure of cash flow information:						
Contingent consideration liability			\$	\$15,700		
Stock acquisition consideration			\$	\$11,265		

# 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 for oncology. Our clinical development efforts center on late-stage oncology assets. We are conducting phase 2 clinical trial of our therapeutic candidate for prostate cancer, PSMA ADC, a fully human monoclonal antibody-drug conjugate (ADC), and have recently completed a phase 2 trial of 1404 (trofolastat), an imaging agent candidate also for prostate cancer. We resumed a pivotal phase 2 clinical trial of Azedra<sup>TM</sup>, our ultra-orphan radiotherapy candidate for pheochromocytoma.

We have licensed our first commercial drug, Relistor ® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation (OIC), to Salix Pharmaceuticals, Inc., which in September 2014 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, outlicenses 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, commercialization milestone and revenue-sharing payments from Salix's Relistor operations. Royalty and milestone payments from Relistor depend on success in development and commercialization, which is dependent on many factors, such as Salix'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.

We fund 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 operations are conducted at our facilities in Tarrytown, New York. We operate under a single research and development segment.

Funding and Financial Matters. At December 31, 2014, we held \$119.3 million in cash and cash equivalents, an increase of \$53.4 million from \$65.9 million at December 31, 2013. 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.

# 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

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 amounts have been reclassified in prior periods' financial statements to conform to the current year presentation. This includes the reclassification of (i) certain expenses for share-based compensation from research and development to general and administrative expenses, (ii) certain non-cash items from general and administrative expenses to intangible impairment charges and change in contingent consideration liability, and (iii) certain expenses from royalty expense to license fees – research and development, which reclassifications had no effect on total expenses as previously reported.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

# Consolidation

The consolidated financial statements include the accounts of Progenics and PSMA LLC, as of and for the years ended December 31, 2014, 2013 and 2012 and Molecular Insight from January 18, 2013, the date we acquired this subsidiary. Inter-company transactions have been eliminated in consolidation.

### **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. The estimate of the classification of deferred revenue as short- or long-term is based upon the period in which we expect to perform joint committee services.

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 and 2012, 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.

During 2014, we have recognized as third quarter revenue a \$40.0 million milestone receivable from Salix upon U.S. marketing approval for subcutaneous Relistor in non-cancer pain patients in September (paid pursuant to the Salix license in October) and a \$1.0 million milestone payment from FUJIFILM RI Pharma in the first quarter of 2014.

During the third quarter of 2014, Salix entered into an agreement with Lupin Limited for distribution of Relistor in Canada. We have not recognized any revenue in 2014, since terms of the Salix and Progenics negotiations were not fixed and determinable as of the end of the year.

Under our 2013 license of certain research, development and commercialization rights to Onalta<sup>TM</sup>, we received a \$0.2 million in upfront payment and are eligible for future milestone and royalty payments. In consideration for the upfront payment, we have delivered relevant know-how (including patent rights), inventory and non-reimbursable services.

In the fourth quarter of 2012, we out-licensed our *C. difficile* program to MedImmune, LLC for a \$5.0 million upfront payment, and the right to receive potential future milestone and royalty payments. In consideration for the upfront payment, we have delivered relevant knowhow (including patent rights) and non-reimbursable services.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

Under our 2012 agreement with CytoDyn Inc. for our PRO 140 program, we received \$3.5 million payment and are eligible for future milestone and royalty payments. In consideration for the upfront payment, we have delivered relevant know-how (including patent rights), inventory and non-reimbursable services.

Under our license agreement, Salix is responsible for further developing and commercializing Relistor worldwide. In consideration of the \$60.0 million upfront payment from Salix, we have granted Salix an exclusive license of relevant know-how, patent rights and technology, assigned relevant third-party contracts, and served on joint committees provided for in the License Agreement through end of 2013.

# **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.

#### **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 Income (Loss) 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 income (loss) by the weighted-average number of common shares outstanding during the period. 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. For 2013 and 2012, 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. As of December 31, 2012, 28 shares of unvested restricted stock outstanding have non-forfeitable rights to dividends; all such shares were vested at the end of December 31, 2013. The allocation of 2013 and 2012 net losses to these participating securities pursuant to the two-class method is not material to both basic and diluted earnings per share.

# **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.

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

# **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, 2014 and 2013, we have invested approximately \$112,808 and \$60,364, respectively, in cash equivalents in the form of money market funds with one major investment company and held approximately \$6,494 and \$5,496, respectively, in two 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, 2014 and 2013 was \$10 and \$7, 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 (see Note 3).

During the fourth quarter of 2014, all of the \$2,208 auction rate securities remaining at December 31, 2013 have been redeemed at par. At December 31, 2013, our investment in auction rate securities (recorded as long-term assets in the Consolidated Balance Sheets) amounted to \$2,208. 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 and Goodwill

The fair values of in-process research and development (IPR&D) 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. 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 independently. These 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. IPR&D intangible assets which are determined to have a decline in their fair value are adjusted downward and an impairment loss is recognized in the Consolidated Statements of Operations. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

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, which includes Molecular Insight), 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, 2014 and 2013.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

In connection with the 2013 acquisition of Molecular Insight, in process research and development and goodwill were initially measured at the acquisition date at estimated fair value and capitalized as an intangible asset, as follows:

- (i) 1404, an imaging agent in phase 2 development, at an estimated fair value of \$23.2 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2017 and a 18% discount rate;
- (ii) Azedra, a small molecule candidate for the treatment of pheochromocytoma and paraganglioma in phase 2b development, and for neuroblastoma in phase 2a development, at an estimated fair value of \$4.9 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2017 and a 15% discount rate;
- (iii) small molecule candidate MIP-1095, in preclinical development for the treatment of prostate cancer, at an estimated fair value of \$2.7 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2021 and a 20% discount rate; and
- (iv) Onalta, a drug candidate in phase 2 development for the treatment of metastatic carcinoid and pancreatic neuroendocrine tumors, at an estimated fair value of \$1.5 million resulting from a probability adjusted discounted cash flow model which includes estimates of significant cash inflows beginning in 2014 and a 15% discount rate.

A third quarter 2014 review of our Onalta intangible asset resulted in a \$560 impairment 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 the finite-lived intangible asset:

	inta	e-lived ngible sets
Balance at January 1, 2013	\$	_
Reclassification from indefinite lived		
IPR&D		21
Amortization expense		(2)
Balance at December 31, 2013		19
Amortization expense		(3)
Impairment		(16)
Balance at December 31, 2014	\$	

The following table reflects, prior to the third quarter write-off, the components of the finite lived intangible assets as of December 31, 2013:

	Gross Amount	cumulated ortization	ľ	Net Carrying Value
Finite lived intangible assets	\$ 21	\$ 2	\$	19
Total	\$ 21	\$ 2	\$	19

The weighted-average remaining life of the finite lived intangible assets was approximately five years at December 31, 2013.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

Amortization expense was calculated on a straight-line basis over the estimated useful life of the asset. Amortization expense for the year ended December 31, 2014 was \$3 and the period from January 18, 2013 to December 31, 2013 was \$2.

The following table summarizes the activity related to the Company's goodwill and indefinite lived IPR&D:

	Goodwill			IPR&D
Balance at January 1, 2013	\$	-	\$	-
Increase related to MIP acquisition		7,702		32,300
Reclassification to finite lived IPR&D		-		(21)
Impairment		_		(919)
Balance at December 31, 2013	\$	7,702	\$	31,360
Impairment		-		(2,660)
Balance at December 31, 2014	\$	7,702	\$	28,700

#### **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 MIP 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.

# Recurring Fair Value Measurements

We believe the carrying amounts of the Company's cash equivalents, accounts receivable, other current assets, other assets (restricted cash providing collateral for a letter of credit securing lease obligations) and accounts payable and accrued expenses approximated their fair values as of December 31, 2014 and 2013 and due to their short-term nature are considered Level 1 instruments.

The fair value of the contingent consideration liability, consisting of future potential milestone payments related to the MIP acquisition was \$17.2 million as of December 31, 2014, \$15.7 million as of December 31, 2013 and \$15.9 million as January 18, 2013, the acquisition date. The fair value of the contingent consideration liability is categorized as a Level 3 instrument, as displayed in Note 3. The Company records the contingent consideration liability at fair value with changes in estimated fair values recorded in the Consolidated Statements of Operations. 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. As of December 31, 2013, we reassessed the fair value of the contingent consideration and recorded a \$0.2 million decrease, due to an increase in the discount period. The December 31, 2014 contingent consideration of \$17.2 million results from probability adjusted discounted cash flows and Monte Carlo simulation models which include estimates of significant milestone payments to former MIP stockholders under the acquisition agreement ranging from 2018 to 2026 and risk adjusted discount rates of 10% and 3.5% for the milestone-based and net sales targets, respectively.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

### 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. 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. An increase in the current discount rate of 0.135% or decrease in the probability of success of 0.194% would result in an impairment of the remaining book value of the MIP-1095 intangible asset. 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. No impairments occurred for the year ended December 31, 2012.

Other current assets are comprised of prepaid expenses, interest and other receivables of \$2,515 and \$1,943 at December 31, 2014 and 2013, respectively, which are expected to be settled within one year. Restricted cash, included in other assets, of \$157 at December 31, 2014 and 2013 consists of collateral for a letter 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.

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	Earlier of life of improvement or
improvements	lease

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

# **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, 2014 and 2013, the Consolidated Balance Sheets include the following:

	2014			2013
Other current liabilities:				
Deferred lease incentive	\$	115	\$	115
Total other current liabilities	\$	\$ 115		
Other liabilities:				
Deferred lease liability	\$	336	\$	224
Deferred lease incentive		575		690
Total other liabilities	\$	911	\$	914

# **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.

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 12).

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

# **Risks and Uncertainties**

We have to date relied principally on external funding, collaborations with Salix, 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 Salix and Fuji fulfilling their manufacturing obligations, either on their own or through third-party suppliers. For 2014, 2013 and 2012, the primary sources of our revenues were Salix, Ono, Fuji, asset out-licensing and disposition, and research grant revenues from the NIH (2013 and 2012). There can be no assurance that revenues from asset out-licensing and disposition, Salix and Fuji will continue. Substantially all of our accounts receivable at December 31, 2014 and 2013 were from the above-named sources.

# **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 income (loss) includes net income (loss) adjusted for the change in net unrealized gain or loss on auction rate securities. The disclosures required by ASC 220 Comprehensive Income for 2014, 2013 and 2012 have been included in the Consolidated Statements of Comprehensive Income (Loss). There was no income tax expense/benefit allocated to any component of Other Comprehensive Income (Loss) (see Note 12).

# **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 Adopted Accounting Standards**

In May 2014, the FASB issued ASU No. 2014-09, 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. Early adoption is not permitted. 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 the prospective impact of the pending adoption 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. Fair Value Measurements

During the fourth quarter of 2014, all of the \$2,208 (net of \$192 unrealized loss) auction rate securities remaining at December 31, 2013 have been redeemed at par.

We record auction rate securities at fair value in the accompanying Consolidated Balance Sheets in accordance with ASC 320 Investments – Debt and Equity Securities. The change in the fair value of these securities is recorded as a component of other comprehensive (loss) income. We also record the contingent consideration liability resulting from the MIP acquisition at fair value in accordance with ASC 820-10-50.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

The following tables present our money market funds, included in cash and cash equivalents, auction rate securities assets in 2013, 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, 2014							
A4	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:	Φ 112.000	Φ 112 000	Ф	Ф					
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					
		Fair Value M	easurements at Dec	ember 31, 2013					
	Balance at December 31, 2013	Fair Value M Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)					
Assets:	December 31,	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs					
Assets: Money market funds	December 31, 2013 \$ 60,364	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs (Level 3)					
1155000	December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)					
Money market funds	December 31, 2013 \$ 60,364	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)					
Money market funds Auction rate securities Total Assets	December 31, 2013 \$ 60,364 2,208	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)					
Money market funds Auction rate securities	December 31, 2013 \$ 60,364 2,208	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)					

At December 31, 2013, we held \$2,208 in auction rate securities which were classified as Level 3. The fair value of these securities included U.S. government subsidized securities collateralized by student loan obligations, with maturities greater than 10 years. We have received all scheduled interest payments on these securities.

The valuation of auction rate securities we held was based on Level 3 unobservable inputs which consisted of our internal analysis of (i) timing of expected future successful auctions or issuer calls of the securities, (ii) collateralization of underlying assets of the security and (iii) credit quality of the security. Due to the 2014 redemption of auction rate securities, the temporary impairment amount of \$192 as of December 31, 2013 has been reversed, which is reflected in the accumulated other comprehensive income (loss) on our accompanying Consolidated Balance Sheets.

The estimated fair value of the contingent consideration liability of \$17,200 as of December 31, 2014, represents future potential milestone payments to former MIP 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.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

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 fair value measurement of the Level 3 inputs as of December 31, 2014 and 2013:

	Dece	Value as of mber 31, 2014	Valuation Technique	Unobservable Input	Range (Weighted Average)
Contingent consideratio	n liabili	ty:			
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	Duck chility of avecage	500/
1404 commercianzation	\$	3,800	model	Probability of success Period of milestone expected achievement	59% 2019
				Discount rate	10%
MIP-1095			Probability adjusted discounted cash flow		
commercialization	\$	400	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%)
vet saies targets	Ψ	10,700	Wone-Caro sinulation	Period of milestone expected achievement	2019 - 2026
				Discount rates (1)	12%/3.5%
	Fair	Value as			
Asset:		of ember 31, 2013	Valuation Technique	Unobservable Input	Range (Weighted Average)
Asset:		ember 31, 2013			(Weighted Average)  5 to 15 years
		mber 31,	Valuation Technique  Discounted cash flow model	Redemption period	(Weighted Average)  5 to 15 years (6 years)
Auction Rate Securities	\$	2,208			(Weighted Average)  5 to 15 years
Auction Rate Securities  Contingent consideratio	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow	Redemption period Discount rate	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)
Auction Rate Securities  Contingent consideratio	\$	2,208	Discounted cash flow model	Redemption period Discount rate  Probability of success	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)
Auction Rate Securities  Contingent consideratio	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow	Redemption period Discount rate  Probability of success Period of milestone expected achievement	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017
Auction Rate Securities  Contingent consideratio	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow	Redemption period Discount rate  Probability of success	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)
Auction Rate Securities  Contingent consideratio  Azedra commercialization	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow	Redemption period Discount rate  Probability of success Period of milestone expected achievement Discount rate	(Weighted Average)  5 to 15 years (6 years)  0.25% - 3.00% (1.55%)  40% 2017 10%
Auction Rate Securities  Contingent consideratio  Azedra commercialization	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow model	Probability of success Period of milestone expected achievement Discount rate  Probability of success	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%
Asset: Auction Rate Securities  Contingent consideration  Azedra commercialization	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow	Redemption period Discount rate  Probability of success Period of milestone expected achievement Discount rate	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%
Auction Rate Securities  Contingent consideration  Azedra commercialization  1404 commercialization	\$ son liabilities \$	2,208 ty: 2,300	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow	Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%  31% 2018 10%
Auction Rate Securities  Contingent consideration  Azedra commercialization  1404 commercialization	\$ on liabili	2,208 ty:	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model	Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%  31% 2018 10%
Auction Rate Securities  Contingent consideratio  Azedra commercialization	\$ son liabilities \$	2,208 ty: 2,300	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow	Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%  31% 2018 10%
Auction Rate Securities  Contingent consideration  Azedra commercialization  1404 commercialization	\$ son liabilities \$	2,208 ty: 2,300	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow	Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%  31% 2018 10%
Auction Rate Securities  Contingent consideration  Azedra commercialization  1404 commercialization  MIP-1095 commercialization	\$ son liabilities \$	2,208 ty: 2,300	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow	Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%  31% 2018 10%
Auction Rate Securities  Contingent consideration  Azedra commercialization  1404 commercialization	\$ son liabilities \$ \$	2,208 ty: 2,300 2,000	Discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model  Probability adjusted discounted cash flow model	Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate  Probability of success Period of milestone expected achievement Discount rate	(Weighted Average)  5 to 15 years (6 years) 0.25% - 3.00% (1.55%)  40% 2017 10%  31% 2018 10%  19% 2021 10%

<sup>(1)</sup> At December 31, 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.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

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

**Asset – Auction Rate Securities** Fair Value Measurements Using Significant **Unobservable Inputs** (Level 3) 2014 2013 **Description** Balance at beginning of period 2,208 3,240 Transfers into Level 3 Total realized/unrealized gains (losses) Included in net income (loss) Included in comprehensive income (loss) 192 68 Settlements (2,400)(1,100)Balance at end of period 2.208 Total amount of unrealized gains (losses) for the period included in other comprehensive income (loss) attributable to the change in fair market value of related assets still held at the reporting date Liability - Contingent Consideration **Fair Value Measurements Using** Significant **Unobservable Inputs** (Level 3) 2014 **Description** 2013 15,700 \$ Balance at beginning of period Fair value of contingent consideration – acquisition of Molecular Insight 15,900 Fair value adjustment to contingent consideration included in net income (loss) 1,500 (200)Balance at end of period 17,200 15,700 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 1,500 (200)

The following tables summarize the amortized cost basis, the aggregate fair value and gross unrealized holding gains and losses at December 31, 2013:

	Aı	Fair	Unrealized Holding							
2013:	C	ost Basis		Value		Gains		(Losses)		Net
Maturities greater than ten years:										
Auction rate securities	\$	2,400	\$	2,208	\$	-	\$	(192)	\$	(192)
	\$	2,400	\$	2,208	\$	_	\$	(192)	\$	(192)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

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 following table shows the gross unrealized losses and fair value of our auction rate securities with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2013.

2013:	Less than	12 Months	12 Months	or Greater	To	Total	
Description of Securities	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	
Auction rate securities	\$ -	\$ -	\$ 2,208	\$ (192)	\$ 2,208	\$ (192)	
Total	\$ -	\$ -	\$ 2,208	\$ (192)	\$ 2,208	\$ (192)	

Other-than-temporary impairment analysis on auction rate securities. The unrealized losses on our auction rate securities resulted from an internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. At December 31, 2013 there was one security with a gross unrealized loss position of \$192 (\$2,208 of the total fair value).

The severity of the unrealized losses for auction rate securities at December 31, 2013 was 8 percent below amortized cost, and the weighted average duration of the unrealized losses for these securities was 70 months.

We have evaluated our individual auction rate securities holdings for other-than-temporary impairment and determined that the unrealized losses as of December 31, 2013 were attributable to uncertainty in the liquidity of the auction rate security market. We did not consider these securities to be other-than-temporarily impaired at December 31, 2013.

#### 4. Accounts Receivable

Our accounts receivable represent amounts due to Progenics from collaborators, royalties, research grants and the sales of research reagents, and as of December 31, 2014 and 2013, consisted of the following:

	 2014	2013
Collaborators	\$ 14	\$ 12
Royalties	40	2,862
Other	 65	 12
	119	2,886
Less, allowance for doubtful accounts	 (10)	(7)
Total	\$ 109	\$ 2,879

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

#### 5. Fixed Assets

Fixed assets as of December 31, 2014 and 2013 consisted of the following:

	 2014	2013
Computer equipment	\$ 1,784	\$ 2,234
Machinery and equipment	5,238	7,091
Furniture and fixtures	116	170
Leasehold improvements	5,027	5,020
Other	208	16
	12,373	14,531
Less, accumulated depreciation and		
amortization	 (9,821)	 (12,118)
Total	\$ 2,552	\$ 2,413

At December 31, 2014 and 2013, \$1.8 million and \$2.0 million, respectively, of leasehold improvements, net were being amortized over periods of 6.4-10.8 years and 8.5-10.8 years, respectively, under leases with terms through December 31, 2020.

#### 6. Accounts Payable and Accrued Expenses

The carrying value of our accounts payable and accrued expenses approximates fair value, as it represents amounts due to vendors and employees, which will be satisfied within one year. Accounts payable and accrued expenses as of December 31, 2014 and 2013, consisted of the following:

	 2014	 2013
Accrued consulting and clinical trial costs	\$ 2,662	\$ 2,672
Accrued payroll and related costs	1,722	2,123
Legal and professional fees	1,063	608
Accounts payable and other	1,040	793
Other	 83	 316
Total	\$ 6,570	\$ 6,512

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

#### 7. 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 <u>Costs</u>	Total Restructuring Accrual
Balance at December 31, 2011	\$ 571	\$ 6	\$ 154	\$ 731
Additions, net	1,905	184	3	2,092
Payments	(1,663)	(190)	(157)	(2,010)
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)		<u> </u>	(359)
Balance at December 31, 2014	\$ -	\$ -	\$ -	\$ -

#### 8. 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.

#### 9. Commitments and Contingencies

#### a. Operating Leases

As of December 31, 2014, we leased office, manufacturing and laboratory space, under lease agreements expiring in December 2020. 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.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

As of December 31, 2014, future minimum annual payments under all operating lease agreements are as follows:

Years ending December 31,	A	inimum annual syments
2015	\$	1,887
2016		1,934
2017		1,983
2018		2,032
2019		2,083
Thereafter		2,135
Total	\$	12,054

Rental expense totaled approximately \$1,864, \$3,548 and \$2,074 for 2014, 2013 and 2012, respectively. For 2014, 2013 and 2012, amounts paid exceeded rent expense by \$3, \$164 and \$419, respectively, due to the recognition of lease incentives. Additional facility charges, including utilities, taxes and operating expenses, for 2014, 2013 and 2012 were approximately \$2,117, \$2,330 and \$2,845, respectively.

#### 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 recognized milestone, license and sublicense fees and supply costs, included in research and development expenses, totaling approximately \$498, \$567 and \$1,170 during the last three years, respectively.

PSMA LLC agreements with:	Paid fro inception Decembe 2014	n to r 31,	_	uture <sup>(1)</sup> nmitments	Terms
Seattle Genetics, Inc.	\$	4,501	\$	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 <sup>®</sup> technology for generating fully human antibodies to PSMA LLC's PSMA antigen.
Former member of PSMA LLC		316		52,197	Annual minimum royalty payments and milestones to use technology related to PSMA.
MIP agreements with :	Paid fro acquisition Decembe 2014	date to r 31,	_	uture <sup>(1)</sup> nmitments	Terms
University of Zurich and the Paul Scherrer Institute	\$	205	\$	1,160	Annual maintenance and license fee payments, milestones and royalties in respect of licensed technology related to 1404.
University of Western Ontario		16		335	Annual minimum royalty, administration and milestone payments in respect of licensed technology related to Azedra.

<sup>(1)</sup> 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.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

In addition, we are planning to out-license or terminate non-germane Molecular Insight licenses and service agreements, as to which we have paid \$151 through December 31, 2014, and have future commitments of \$14,425, subject to occurrence of future milestones or events. In February 2015 we have terminated one of Progenics' license agreements in respect of oncology and other products, as to which we paid \$909 through December 31, 2014, and had future commitments of \$777, subject to occurrence of 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 \$67, \$39 and \$8 for 2014, 2013 and 2012, respectively. Those expenses include the fair value of stock options granted during 2013, of approximately \$17 and \$7 for 2014 and 2013, respectively. Such amounts of fair value are included in research and development expense for each year presented (see Note 10).

#### d. Retirement Agreement

On March 14, 2012, Progenics and company founder Paul J. Maddon entered into an agreement providing for his retirement as Chief Science Officer. In connection with Dr. Maddon's retirement and termination of his employment agreement, Progenics agreed to pay him an amount equal to \$1,789 and provide other benefits under the agreement.

#### e. 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, on customary terms and conditions, whereby, in 2013, MTS has 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.

#### f. Legal Proceedings

Progenics is a party to a proceeding brought by a former employee complaining that the Company violated the anti-retaliation provisions of the federal Sarbanes-Oxley law by terminating the former employee. The Company believes the former employee's claims are without merit and is contesting the matter vigorously. The federal District Court hearing the case issued in July 2013 an order denying our motion for summary judgment dismissing the former employee's complaint, making it likely that the proceeding will continue to trial. Given the uncertainty attendant to the proceeding, we have accrued amounts in connection with this matter which are not material to these Consolidated Financial Statements.

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 has been recorded as other operating income.

#### 10. 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.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

(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, 2014, 2013 and 2012, 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 2014, 2013 and 2012 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 7.5 years, 5.3 and 7.4 years and 5.4 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 2014, 2013 and 2012:

_	2014	2013	2012
Expected volatility	74% - 84%	73% – 90%	70% - 85%
Expected dividends	Zero	Zero	Zero
Expected term (years)	5.3 - 7.5	5.3 - 10	5.3 - 10
Weighted average expected term (years)	5.93	5.96	6.11
Risk-free rate	1.64% –	0.76% –	0.57% –
	2.42%	2.83%	1.71%

#### 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, 2014 and changes during the year then ended is presented below:

Options	Shares	Av Ex	eighted verage sercise Price	Weighted Average Remaining Contractual Term (Yr.)	ggregate ntrinsic Value
Outstanding at January 1, 2014	5,249	\$	10.94		
Granted	993		4.66		
Exercised	(77)		5.54		
Forfeited	(324)		6.00		
Expired	(423)		13.52		
Outstanding at December 31, 2014	5,418		9.96	5.79	\$ 6,856
Exercisable at December 31, 2014	4,115	\$	11.40	4.89	\$ 3,798

The weighted average grant-date fair value of options granted under the Plans during 2014, 2013 and 2012 was \$3.41, \$3.74 and \$6.38, respectively. The total intrinsic value of options exercised during 2014, 2013 and 2012 was \$102, \$11 and \$174, 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, 2014, the estimated requisite service period for the 2006 award was 1.5 years. For 2014, 2013 and 2012, the total compensation expense recognized for the performance-based options was \$0.1 million, \$0.1 million and \$2.0 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 2014, 2013 and 2012 was:

	2	2014		2013		2012
Recognized as:						
Research and						
Development	\$	1,843	\$	2,012	\$	4,060
General and						
Administrative		1,680		1,534		2,476
Total	\$	3,523	\$	3,546	\$	6,536

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, 2014, there was \$3.2 million of total unrecognized compensation cost 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 2 years. Cash received from exercises under all share-based payment arrangements for 2014 was \$0.4 million. We issue new shares of our common stock upon share option exercises.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

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. We reported net income for 2014 and included the dilutive effect of unrecognized compensation expense in the assumed proceeds in the denominator of the diluted EPS calculation. The shares to be issued upon the assumed conversion of the contingent consideration liability in 2014 and 2013 have been excluded from the calculation of diluted earnings per share, as their effect would have been anti-dilutive. We incurred net losses for 2013 and 2012 and, therefore, such amounts have not been included in the calculations for those periods since they would be anti-dilutive. As a result, basic and diluted EPS are the same for the 2013 and 2012 periods. 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.

#### 11. 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. During the three years ended December 31, 2014, we matched 50% of those employee contributions that are equal to 5%-8% of compensation and are 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 \$276, \$330 and \$535 to the Amended Plan for 2014, 2013 and 2012, respectively. No discretionary contributions were made during those years.

#### 12. 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 2014, 2013 and 2012, other than \$1.0 million and \$0.4 million income tax benefit in 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.

Deferred tax assets and liabilities as of December 31, 2014 and 2013, consisted of the following:

	2014		2013	
Deferred tax assets:				
Depreciation and amortization	\$	5,770	\$	6,165
R&E tax credit carry-forwards		5,270		5,025
NYS investment tax credit carry-forwards		1,090		1,095
AMT credit carry-forwards		211		211
Net operating loss carry-forwards		204,974		190,263
Capitalized research and development				
expenditures		20,280		25,231
Stock compensation		13,848		13,826
Other items		-		1,097
Total gross deferred tax assets		251,443		242,913
Less: Valuation allowance		(251,443)		(242,913)
Deferred tax assets		-		-
Deferred tax liability – long term		(11,332)		(12,321)
Net deferred tax liability	\$	(11,332)	\$	(12,321)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

We do not recognize 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 2014, 2013 and 2012, we incurred net losses for tax purposes. We recognized a full tax valuation against deferred tax assets at December 31, 2014 and 2013. In 2014 and 2013 we recognized deferred income tax liabilities of \$11,332 and \$12,321, respectively to reflect the net tax effects of temporary differences between the carrying amounts of in process research and development assets for financial reporting purposes and the amounts used for income tax purposes.

The following is a reconciliation of income taxes computed at the Federal statutory income tax rate to the actual effective income tax provision during 2014, 2013 and 2012:

	2014 2013		2012
		_	
U.S. Federal statutory rate	34.0%	(34.0)%	(35.0)%
State income taxes, net of			
Federal benefit	13.2	(4.9)	(5.4)
Research and experimental tax			
credit	(15.8)	(3.8)	-
Effect of federal and state tax			
rate changes	1.5	8.7	-
Permanent differences	47.9	3.2	4.2
Change in valuation allowance	(109.6)	30.0	36.2
Income tax (benefit)	(28.8)%	(0.8)%	0.0%

As of December 31, 2014, we had available, for tax return purposes, unused federal NOLs of approximately \$557.2 million, which will expire in various years from 2018 to 2034, \$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, \$11.2 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 \$475.6 million, which will expire in various years from 2018 to 2034.

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 development credit carry-forwards. Such a study might result in an adjustment to our research and development 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 development 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, 2014, we are subject to federal and state income tax in the U.S. 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, 2014, 2013 and 2012.

Our research and experimental (R&E) tax credit carry-forwards of approximately \$5.3 million at December 31, 2014 expire in various years from 2018 to 2034.

As of December 31, 2014 and 2013, 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.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2014 and 2013.

	2014			2013
Beginning uncertain tax benefits	\$	2,661	\$	2,661
Current year - increases	Ψ	-	Ψ	2,001
Current year - decreases		-		-
Settlements		_		-
Expired statuses		<u>-</u>		-
Ending uncertain tax benefits	\$	2,661	\$	2,661

#### 13. Net Income (Loss) Per Share

Our basic net income (loss) per share amounts have been computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period. 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 amount 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. For 2013 and 2012, we reported net losses and, therefore, potential common shares were not included since such inclusion would have been anti-dilutive. As of December 31, 2012 our 28 shares of unvested restricted stock with non-forfeitable rights to dividends were outstanding; all such shares were vested at the end of December 31, 2013. The allocation of 2012 net losses to these participating securities pursuant to the two-class method is not material to both basic and diluted earnings per share. The calculations of net loss per share, basic and diluted, are as follows:

2014:	imerator)	Weighted Average Common Shares (Denominator)	Per Share Amount
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)
2012:			
Basic and diluted	\$ (35,431)	34,754	\$ (1.02)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - continued

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

During 2014, 2013 and 2012, anti-dilutive common shares excluded from diluted per share amounts consist of the following:

	2014			20	13		2012			
	Weighted Weighted Average Average Number Exercise Price		Weighted Average Number	Weighted Average Exercise Price		Weighted Average Number	Weighted Average Exercise Price			
Options	5,036	\$	10.56	5,969	\$	11.54	5,947	\$	12.32	
Contingent consideration liability	3,457			3,544			-			
Restricted stock	_						60			
Total	8,493			9,513			6,007			

#### 14. Unaudited Quarterly Results (unaudited)

Summarized quarterly financial data during 2014 and 2013 are as follows:

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

	2013 Quarter Ended								
		March 31		June 30		September 30		December 31	
Revenues	\$	2,226	\$	1,801	\$	867	\$	2,968	
Net loss		(11,258)		(12,263)		(10,500)		(8,551)	
Net loss per share - basic and diluted		(0.22)		(0.24)		(0.17)		(0.14)	

<sup>(1)</sup> Revenues in the first and third quarters of 2014 include \$1.0 million milestone revenue from Fuji and \$40.0 million milestone revenue from Salix, respectively.

#### SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

#### **Allowance for Doubtful Accounts**

Year ended December 31, (in thousands)	Beginning I	Balance	Additions Charged to Gene and administrat expenses		Deductions Accounts Writt Off During Per		Ending	g Balance
2014	\$	7	\$	3	\$	-	\$	10
2013	\$	-	\$	7	\$	_	\$	7

#### **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 16, 2015

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.

<b>Signature</b>	Capacity	<u>Date</u>
/s/ PETER J. CROWLEY Peter J. Crowley	Chairman	March 16, 2015
/s/ PAUL J. MADDON Paul J. Maddon, M.D., Ph.D.	Vice Chairman	March 16, 2015
/s/ MARK R. BAKER Mark R. Baker	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2015
/s/ KAREN J. FERRANTE Karen J. Ferrante, M.D.	Director	March 16, 2015
/s/ MICHAEL D. KISHBAUCH Michael D. Kishbauch	Director	March 16, 2015
/s/ DAVID A. SCHEINBERG David A. Scheinberg, M.D., Ph.D.	Director	March 16, 2015
/s/ NICOLE S. WILLIAMS Nicole S. Williams	Director	March 16, 2015
/s/ ANGELO W. LOVALLO, JR. Angelo W. Lovallo, Jr.	Vice President, Finance and Treasurer (Principal Financial and Accounting Officer)	March 16, 2015

#### **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‡
10.9(3)	Letter dated August 25, 1994 between the Registrant and Dr. Robert J. Israel‡
10.16(9)†	Development and License Agreement, dated April 30, 1999, between Protein Design Labs, Inc. and the Registrant.
10.16.1(10)	Letter Agreement, dated November 24, 2003, relating to the Development and License Agreement between Protein Design
	Labs, Inc. and the Registrant.
10.19(11) †	Exclusive Sub-license Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.19.1(12)	Amendment to Exclusive Sub-license Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.21.1(13)	Amended and Restated Agreement of Lease, dated October 28, 2009, between BMR-Landmark at Eastview LLC and the
	Registrant.
10.23	Information concerning compensation of the Registrant's non-employee directors is included in the Registrant's proxy material
	for its 2013 Annual Meeting of Stockholders and its Current Report on Form 8-K filed on September 12, 2013 and is
10.05(1.4)	incorporated herein by reference.‡
10.25(14) †	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(15)	Membership Interest Purchase Agreement, dated April 20, 2006, between the Registrant Inc. and Cytogen Corporation.
10.27(15) †	Amended and Restated PSMA/PSMP License Agreement, dated April 20, 2006, by and among the Registrant, Cytogen
10.27(13)	Corporation and PSMA Development Company LLC.
10.29(16) †	License Agreement, dated as of October 16, 2008, by and among Ono Pharmaceutical Co., Ltd. and the Registrant.
10.34(17) †	Collaboration Agreement, effective June 14, 2005, by and between Seattle Genetics, Inc. and PSMA Development Company,
\ / '	LLC.
10.37(18) †	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(18) †	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(19) †	Stock Purchase and Sale Agreement, dated January 16, 2013, by and between Molecular Insight Pharmaceuticals, Inc., its
10.00(10)	Stockholders, the Registrant, and Highland Capital Management, L.P., as Stockholders Representative.
10.39(19) †	License Agreement, dated September 1, 2012, by and between FUJIFILM RI Pharma Co., Ltd. and Molecular Insight
10 40(20) +	Pharmaceuticals, Inc.
10.40(20) †	License Agreement, dated May 4, 2012, between Molecular Insight Pharmaceuticals, Inc., the University of Zurich and the
10.41(21)	Paul Scherrer Institute. License Agreement, dated as of December 15, 2000, between Molecular Insight Pharmaceuticals, Inc. and The Board of
10.41(21)	Governors of the University of Western Ontario.
10.42(21)	License Agreement, dated as of November 3, 2006, between Molecular Insight Pharmaceuticals, Inc. and Novartis Pharma AG,
10.42(21)	together with First Amendment, dated January 4, 2007, thereto.
10.43(22)	Controlled Equity Offering SM Sales Agreement dated as of January 23, 2014, by and between the Registrant and Cantor
105(22)	Fitzgerald & Co.
10.44(23)	Agreement, dated September 19, 2014, between the Registrant and Dr. Hagop Youssoufian.‡
10.45(17) †	Collaboration Agreement, effective February 21, 2001, by and between Abgenix, Inc. and PSMA Development Company,
` / '	LLC.
12.1	Statement re computation of ratio of earnings (loss) to combined fixed charges and preferred stock dividends.
21.1	Subsidiaries of the Registrant.

#### **Table of Contents**

101.DEF

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 Angelo W. Lovallo, Jr., Vice President, Finance & Treasurer 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 Angelo W. Lovallo, Jr., Vice President, Finance & Treasurer 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

- \* 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.

XBRL Taxonomy Extension Definition Document

- (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 Ouarterly Report on Form 10-O for the quarter ended June 30, 1999.
- (10) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2004.
- (11) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2002.
- (12) Previously filed in Current Report on Form 8-K filed on September 20, 2004.
- (13) Previously filed in Current Report on Form 8-K filed on November 28, 2012.
- (14) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2005.
- (15) Previously filed in Quarterly Report on Form 10-Q for the quarter ended June 30, 2006
- (16) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2008.
- (17) Previously filed in Amendment No. 2 to Annual Report on Form 10-K/A for the year ended December 31, 2009.
- (18) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.
- (19) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.
- (20) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2013.
- (21) Previously filed in Registration Statement on Form S-1, Commission File No. 333-129570 filed by Molecular Insight Pharmaceuticals, Inc.
- (22) Previously filed in Registration Statement on Form S-3, Commission File No. 333-193521.
- (23) Previously filed in Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.
- † Confidential treatment granted as to certain portions omitted and filed separately with the Commission.
- ‡ Management contract or compensatory plan or arrangement.

# Progenics Pharmaceuticals, Inc. Ratio of Earnings (Loss) to Combined Fixed Charges and Preferred Stock Dividends (in thousands)

Years Ended December 31, 2014 2013 2012 2011 2010 Determination of earnings (loss): \$ 4,410 (42,934) \$ (35,431) \$ 10,381 (69.820) Income (loss) from operations Add: Fixed charges 373 710 410 695 709 Earnings (loss), as adjusted \$ 4,783 \$ (42,224) \$ (35,021) \$ 11,076 (69,111)Fixed charges: Estimate of interest within rental expense 373 710 410 695 709 Fixed charges \$ 373 \$ 710 \$ 410 \$ 695 \$ 709 \$ Preferred stock dividends \$ \$ \$ \$ Ratio of earnings (loss) to fixed charges and preferred \* stock dividends 13 16 Coverage deficiency amount for total fixed charges and preferred stock dividends (1) \$ \$ 42,934 \$ \$ \$ 35,431 69,820

<sup>(1)</sup> For the years ended 2010, 2012 and 2013, the Company's coverage ratio is less than one-to-one and it must generate additional earnings of these specified amounts to achieve a coverage ratio of 1:1.

#### **Progenics Pharmaceuticals, Inc.**

Subsidiaries

#### Name Jurisdiction of Incorporation

Excelsior Life Sciences Ireland Limited	Ireland	
Molecular Insight Pharmaceuticals, Inc.	Delaware	
Molecular Insight Limited*	England and Wales	
Progenics Life Sciences Limited	England and Wales	
Progenics Pharmaceuticals Nevada, Inc.	Nevada	
PSMA Development Company LLC	Delaware	

<sup>\*</sup> Subsidiary of Molecular Insight Pharmaceuticals, Inc.

#### **Consent of Independent Registered Public Accounting Firm**

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

- (1) Registration Statement (Form S-3 No. 333-193521) including the related Prospectus and Prospectus Supplement;
- (2) Registration Statements (Form S-8 Nos. 333-183511, 333-124910, 333-143670, 333-160389, 333-176204 and 333-197071) pertaining to the 2005 Stock Incentive Plan;
- (3) Registration Statements (Form S-8 Nos. 333-52277 and 333-120508) pertaining to its Amended and Restated 1996 Stock Incentive Plan;

of our reports dated March 16, 2015, with respect to the consolidated financial statements and schedule of Progenics Pharmaceuticals, Inc., and the effectiveness of internal control over financial reporting of Progenics Pharmaceuticals, Inc., included in the Company's Annual Report (Form 10-K) for the year ended December 31, 2014.

/s/ Ernst & Young LLP Hartford, Connecticut March 16, 2015

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

#### I, Mark R. Baker, certify that:

- 1. I have reviewed this annual report on Form 10-K of Progenics Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
    about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on
    such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's independent registered public accounting firm and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Mark R. Baker

Date: March 16, 2015

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

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

I, Angelo W. Lovallo, Jr., certify that:

- 1. I have reviewed this annual report on Form 10-K of Progenics Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
    about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on
    such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's independent registered public accounting firm and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Angelo W. Lovallo, Jr.

Date: March 16, 2015

Angelo W. Lovallo, Jr.

Vice President, Finance & Treasurer
(Principal Financial and Accounting Officer)

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

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

This annual report on Form 10-K of the Company for the period ended December 31, 2014 and filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Mark R. Baker

Date: March 16, 2015

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

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

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

The undersigned Vice President, Finance & Treasurer of Progenics Pharmaceuticals, Inc. (the "Company") does hereby certify as follows:

This annual report on Form 10-K of the Company for the period ended December 31, 2014 and filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Angelo W. Lovallo, Jr.

Angelo W. Lovallo, Jr.
Vice President, Finance & Treasurer
(Principal Financial and Accounting Officer)

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

Date: March 16, 2015