

PROGENICS PHARMACEUTICALS INC  
Form 10-K  
March 15, 2013

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

FORM 10-K  
(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2012  
Or  
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 000-23143

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:  
Title of each class Name of each exchange on which registered  
Common Stock, par value \$0.0013 per share The NASDAQ Stock Market LLC

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

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

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant on June 30, 2012, based upon the closing price of the Common Stock on The NASDAQ Stock Market LLC on that date of \$9.78 per share, was \$184,846,567 <sup>(1)</sup>.

Calculated by excluding all shares that may be deemed to be beneficially owned by executive officers, directors and <sup>(1)</sup>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 8, 2013, a total of 51,131,349 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 2013 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; 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, 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<sup>®</sup> 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 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.

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Item 1. Business

Progenics Pharmaceuticals develops innovative medicines for oncology. A significant part of our research and development efforts centers on prostate specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. We are conducting phase 2 clinical trials of two product candidates for prostate cancer: our therapeutic candidate, PSMA ADC, a fully human monoclonal antibody-drug conjugate (ADC) directed toward PSMA and designed to deliver targeted chemotherapy to cancer cells, and MIP-1404, an imaging agent candidate with potential to alter clinical practice in treating prostate cancer in development by Molecular Insight Pharmaceuticals, a clinical-stage biotechnology company we acquired this January. Among other assets in our pipeline of targeted radiotherapy and molecular imaging compounds from the acquisition are a group of small molecule therapeutics, MIP-1095, -1555 and -1558, in preclinical study for metastatic prostate cancer and other PSMA-expressing cancers, and Azedra™, an ultra-orphan radiotherapy candidate in phase 2 study for pheochromocytoma and potential additional indications.

Progenics has developed internally and acquired from research institutions, pharmaceutical and biotechnology companies compounds and technologies which we determine to advance with other parties, including our first commercial drug, Relistor® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation, which we have licensed to Salix Pharmaceuticals, Inc. worldwide other than Japan, where we have licensed the subcutaneous formulation of the drug to Ono Pharmaceutical Co., Ltd. We have also recently out-licensed to MedImmune, LLC our proprietary *C. difficile* research program, and transferred our PRO 140 HIV viral-entry inhibitor to CytoDyn Inc. for upfront cash, milestones and royalties. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving our proprietary research, development and clinical programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

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ONCOLOGY

Clinical

~~Proposed~~ proposed indication candidates

Status

PSMA  
ADC

Treatment of prostate and other cancers

Phase 2 testing ongoing

~~Imaging agent for prostate cancer~~  
Imaging agent for prostate cancer

Phase 2 testing ongoing

Imaging agent for prostate cancer (Japan)

In development by FUJIFILM RI Pharma

~~Treatment of pheochromocytoma (ultra-orphan) and paraganglioma~~  
Azedra™  
Treatment of pheochromocytoma (ultra-orphan) and paraganglioma

Phase 2b registrational trial under Special Protocol Assessment

Neuroblastoma

Phase 2a testing completed

Research

Small molecule therapeutics

~~Imaging agent for prostate cancer~~  
(~~1555 and 1558~~)  
-1555 and -1558)

Preclinical

RELISTOR®

Marketed

~~Approved~~ approved indication product

Status

~~Treatment of opioid induced constipation (OIC) in advanced-illness patients receiving palliative care when laxative therapy has not been sufficient~~  
Relistor-Subcutaneous injection

Marketed in the U.S., E.U., Canada, Australia and elsewhere; Licensed to Salix Pharmaceuticals worldwide other than Japan

Clinical

~~Proposed~~ proposed indication candidates

Relistor-Subcutaneous  
Treatment of OIC in patients with non-cancer pain injection

Complete Response Letter received on pending sNDA

Relistor-Subcutaneous  
Treatment of OIC (Japan) injection

In development by Ono Pharmaceutical

~~Relston Oral OIC~~

Phase 3 testing completed

PARTNERED PROGRAMS

Proposed indication

Status

PRO  
140  
Treatment of Human Immunodeficiency Virus (HIV) infection Partnered with CytoDyn; phase 2

Anti-C.  
difficile  
monoclonal  
antibodies  
Treatment of conditions caused by Clostridium difficile toxins Partnered with MedImmune; phase 2

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### Notes:

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. The approved U.S. label for Relistor also provides that use of Relistor beyond four months has not been studied. Full U.S. prescribing information is available at [www.Relistor.com](http://www.Relistor.com). Other approved labels for Relistor apply in ex-US markets. Azedra is a trademark of Molecular Insight.

In summarizing the status of our commercialization and product candidates:

Research and discovery means initial research related to specific molecular targets, synthesis of new chemical entities, assay development or screening for identification and optimization of lead compound(s). This work precedes preclinical investigations, which involves lead compound(s) undergoing toxicology, formulation and other testing in preparation for clinical trials.

Phase 1-3 clinical trials are safety and efficacy tests in humans:

- 1: Initial evaluation of safety in humans; study method of action and metabolism.
- 2: Evaluation of safety, dosing and activity or efficacy; continue safety evaluation.
- 3: Larger scale evaluation of safety, efficacy and dosage.

### Oncology

A significant part of our oncology efforts involves research and development directed at prostate specific membrane antigen, or PSMA, a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. Our main product candidate in these efforts is our fully human monoclonal antibody-drug conjugate, PSMA ADC, which is designed to deliver a chemotherapeutic agent to cancer cells by targeting the three-dimensional structure of the PSMA protein on these cells and binding to and internalizing within the cell. PSMA ADC utilizes our own technology together with intellectual property licensed to us from Sloan-Kettering Institute for Cancer Research and Seattle Genetics, Inc. We are conducting a phase 2 open-label, multicenter clinical trial of this compound to assess anti-tumor activity, tolerability and safety in up to 75 patients with metastatic castration-resistant prostate cancer.

Through our recent acquisition of Molecular Insight (MIP), we have significantly expanded our focus on PSMA as an oncology target while broadening our oncology pipeline with its targeted radiotherapy and molecular imaging compounds, including:

MIP-1404, a radio-labeled small molecule which binds PSMA and acts as an imaging agent to diagnose and detect prostate cancer, including in other soft tissue and bone. An ongoing phase 2 global multicentered study is assessing the diagnostic accuracy of MIP-1404 imaging in men with high-risk prostate cancer scheduled for radical prostatectomy and extended pelvic lymph node dissection compared to histopathology. MIP has out-licensed MIP-1404 to FUJIFILM RI Pharma Co., Ltd. for development and commercialization in Japan.

MIP-1095, -1555 and -1558, small molecules in preclinical development as a therapeutic for metastatic prostate cancer and other PSMA-expressing cancers targeting the PSMA antigen with a radioactive payload. It has generated evidence of dose-dependent enhanced tumor kill and prolonged survival in animal models of human prostate cancer, and an ongoing investigator-initiated study in Germany of men with late-stage metastatic prostate cancer

demonstrated tumor reduction for more than 14 days and a greater than 50% decrease in prostate-specific antigen (PSA, a secreted protein that is distinct from PSMA) levels in eight of 14 evaluable patients.

Azedra, a phase 2 radiotherapeutic product candidate in development as a treatment for pheochromocytoma -- rare tumors found primarily in the adrenal glands (called paraganglioma elsewhere) -- in adults, and neuroblastoma in children. Azedra has Orphan Drug designation and Fast Track status in the United States and European Union Orphan Drug designation for the treatment of neuroblastoma. If approved, Azedra would be the first therapeutic in the U.S. for the treatment of pheochromocytoma. Azedra utilizes MIP's own technology together with intellectual property licensed to it from the University of Western Ontario and McMaster University.

We have recently suspended investment in our proprietary phosphoinositide 3-kinase (PI3K) inhibitor research and are evaluating alternative paths forward for this program. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving our proprietary research, development and clinical programs, and may in the future also in-license or acquire additional oncology compounds and/or programs.

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## 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 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 indications (such as OIC in patients with chronic, non-cancer pain) and formulations of the drug (such as an oral formulation of methylnaltrexone, the active ingredient in Relistor). As previously announced, the U.S. Food and Drug Administration last July issued a Complete Response Letter for the supplemental New Drug Application for Relistor injection for subcutaneous use for the treatment of OIC in adult patients with chronic, non-cancer pain. Salix and Progenics are continuing to work together and with the FDA to generate a reasonable path forward for the further development and regulatory review of Relistor, and while it is not possible to determine definitively the duration of discussions with the FDA regarding this matter, at this time Salix and Progenics anticipate a path forward could be reached with the FDA during 2013. See Risk Factors.

Relistor net sales and related royalties earned during the years 2010-2012 are set forth below. Our recognition of royalty revenue 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 commercialization collaborators.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
	(in thousands)				
2012:					
Net Sales	\$ 12,300	\$ 10,800	\$ 4,900	\$ 5,200	\$ 33,200
Royalties Earned	1,834	1,619	728	782	4,963
2011:					
Net Sales	\$ 3,300	\$ 5,200	\$ 9,700	\$ 8,800	\$ 27,000
Royalties Earned	-	527	1,240	1,279	3,046
2010:					
Net Sales	\$ 4,200	\$ 3,800	\$ 4,100	\$ 4,000	\$ 16,100
Royalties Earned	625	581	620	-	1,826

## 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 and will utilize technology licensed to us from Sloan-Kettering. 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® 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 4,566,210 shares of Progenics common stock (with 500,000 held in escrow) 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 all MIP products. The agreement contains customary representations and warranties, covenants, and indemnification and other provisions.

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### Relistor

Under our License Agreement, Salix Pharmaceuticals is responsible for further developing and commercializing subcutaneous Relistor worldwide other than Japan, 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. 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 and for which we are obligated to make milestone and royalty payments to the University. Salix is paying us royalties ranging from 15 to 19 percent on its net sales of Relistor as well as 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold and territory-specific research and development expense reimbursement) it receives from sublicensees in respect of any country outside the U.S. We are also eligible to receive (i) a development milestone of up to \$40 million upon U.S. marketing approval for subcutaneous Relistor in chronic, non-cancer pain patients (the proposed indication addressed in the Complete Response Letter referred to above), (ii) a development milestone of up to \$50 million upon U.S. marketing approval of an oral formulation of Relistor, and (iii) up to \$200 million of commercialization milestone payments upon achievement of specified U.S. sales targets. In the event that either marketing approval 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 subject, to achievement of the first commercialization milestone payable upon annual U.S. sales first exceeding \$100 million. See Risk Factors.

We have licensed to Ono Pharmaceutical the rights to subcutaneous Relistor in Japan, where Ono is responsible for developing and commercializing subcutaneous Relistor, including conducting clinical development to support regulatory marketing approval and will own the subcutaneous filings and approvals relating to Relistor. We are entitled to receive up to \$20 million upon achievement of development milestones as well as royalties and commercialization milestones on sales of subcutaneous Relistor in Japan. Ono has the option to acquire the rights to develop and commercialize other formulations of Relistor in Japan, on terms to be negotiated separately. Supervision of and consultation with respect to Ono's development and commercialization responsibilities are carried out by joint committees. The Ono License contains, among other terms, provisions which permit termination by either party upon the occurrence of certain events.

### 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.

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

Clinical and Research Candidates; Relistor	Number of Patents		Expiration Dates <sup>(1)</sup>	Number of Patent Applications	
	U.S.	International		U.S.	International
Oncology (PSMA; key MIP programs)	13	7	2013-2029	20	90
Relistor	10	34	2015-2030	26	206
Other	13	60	2016-2023	3	29

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

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. Product candidates must generally be manufactured according to current Good Manufacturing Practices (cGMP), and pre-clinical safety tests must be conducted by laboratories that comply with FDA good laboratory practices regulations.

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Results of pre-clinical tests are submitted to the FDA as part of an Investigational New Drug application (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 (ICH) 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 pre-clinical and clinical testing process, the approval process, or thereafter, may result in various adverse consequences, including FDA delay in approving or refusal to approve a product, withdrawal of an approved product from the market or the imposition of criminal penalties against the manufacturer or sponsor. Later discovery of previously unknown problems may result in restrictions on the product, manufacturer or sponsor, including withdrawal of the product from the market.

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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 Ono is responsible for developing and commercializing the subcutaneous form of Relistor and 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. See Risk Factors.

We expect to engage third-party CMOs to manufacture additional clinical trial supplies of our PSMA monoclonal antibody and to continue using CMOs for other portions of the PSMA ADC manufacturing process. If we are unable to arrange for satisfactory CMO services, or otherwise were to determine to establish a new manufacturing capacity, we would need to expand our manufacturing staff and facilities or obtain new facilities. In order to establish a full-scale commercial manufacturing facility for any of our product candidates, we would need to spend substantial additional funds, hire and train significant numbers of employees and comply with the extensive FDA regulations applicable to such a facility.

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.

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Competition

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

Relistor 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. 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 has filed an sNDA, which has been granted priority review by the FDA, for approval of this drug for opioid-induced constipation. A Nektar Therapeutics-AstraZeneca PLC collaboration is conducting phase 3 efficacy and safety studies of an oral peripheral mu-opioid receptor antagonist in patients with OIC, and has a related combination product in early stage development. Theravance, Inc. has completed phase 2 clinical testing of an oral peripheral mu-opioid antagonist. In Europe, Mundipharma International Limited markets TARGIN® (oxycodone/naloxone), a combination of an opioid and a systemic opioid antagonist. Other prescription as well as over-the-counter (OTC) constipation products are also prescribed first line for OIC.

As to our oncology pipeline, radiation and surgery are two traditional forms of treatment for prostate cancer. If the disease spreads, hormone (androgen) suppression therapy is often used to slow the cancer's progression, but this form of treatment can eventually become ineffective. We are aware of several competitors who are developing or have received approval for alternative treatments for castration-resistant prostate cancer, some of which are directed against PSMA, including Johnson & Johnson subsidiary Janssen Biotech, Inc.'s Zytiga® (abiraterone acetate), approved in 2011 for use in combination with prednisone as a second-line (after treatment with docetaxel) advanced prostate cancer treatment, and in December 2012 for use with prednisone for metastatic castration-resistant disease before the use of chemotherapy); Medivation, Inc.'s Xtandi® (enzalutamide), approved in August 2012 for patients with metastatic castration-resistant prostate cancer previously treated with docetaxel; and Algeta ASA's Alpharadin® (radium-223 chloride), submitted in late 2012 for marketing authorization for therapy of bone metastases in prostate cancer patients. A competitive product to MIP-1404 is Jazz Pharmaceuticals' ProstaScint®, which is approved for detection of metastatic prostate cancer or relapsed or high-risk prostate cancer patients.

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.

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Human Resources

At December 31, 2012, we had 76 full-time employees, 15 of whom hold Ph.D. degrees and one an M.D. degree. At that date, 57 employees were engaged in research and development, medical, regulatory affairs and manufacturing related activities and 19 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, including the programs and product candidates we have recently acquired in the Molecular Insight transaction.

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, including those we have recently acquired in the Molecular Insight transaction, involve novel approaches to human therapeutics. Our product candidates, including those we have recently acquired as part of MIP, are in pre-clinical or 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 pressures such as those experienced worldwide over the recent past. With our strategy to focus on oncology research and development, these risks continue to be significant and may increase to the extent the oncology space becomes more competitive or less favored in the commercial marketplace.

Our integration of the Molecular Insight acquisition will continue to require significant efforts, including coordination of research and development, as well as finance, accounting, and information technology and other functions, all of which involve expense and significant management time. The success of this acquisition will depend on, among other things, the strength of MIP's product candidates and their underlying technologies; results of clinical trials, regulatory applications and approvals; and our ability to fund or otherwise develop acquired candidates and programs, achieve available cost savings, efficiencies and synergies, and attract and retain employees and consultants with expertise and experience appropriate to these efforts. Our failure to manage successfully the MIP acquisition or any of the acquired 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, Ono 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 and, in the Japanese market, we rely on Ono to conduct clinical trials and obtain regulatory approvals. We are and will be dependent upon Salix, Ono and any other business partners with which we may collaborate in the future to perform and fund development, including clinical testing of Relistor, make related regulatory filings and manufacture and market 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. Ono will have similar discretion with respect to sales in Japan. Neither may 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, Ono 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. We may have future disagreements with Salix or Ono, both of which have significantly greater financial and managerial resources which either 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 and/or Ono concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property, including Relistor's path forward in light of the July, 2012 Complete Response Letter from the FDA. For example, Salix has disclosed in regulatory filings that it might terminate its development program Relistor subcutaneous injection for treatment of OIC in chronic non-cancer pain patients, and that additional information and additional guidance from the FDA could result in the termination of its oral OIC Relistor development program.

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We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated fines and delays.

Our business, products and product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries. These agencies and other entities regulate the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, recordkeeping, advertising, promotion and other aspects of our products and product candidates. We cannot guarantee that approvals of product candidates, processes or facilities will be granted on a timely basis, or at all. If we experience delays or failures in obtaining approvals, commercialization of our product candidates will be slowed or stopped. Even if we obtain regulatory approval, the approval may include significant limitations on indicated uses for which the product could be marketed or other significant marketing restrictions, such as a Risk Evaluation and Mitigation Strategy (REMS). For example, Relistor is only approved for OIC in patients with advanced illness and not for chronic, non-cancer pain.

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 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 in the process of responding to the subpoena and intends to cooperate fully with the subpoena and related government investigation, 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, and that the laws and regulations regarding off-label promotion and the authorities' interpretation of them might increase its expenses, impair its ability to effectively market its products, and limit its revenue.

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 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 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 Ono's ability to compete effectively in the market.

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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, including those we have acquired in the Molecular Insight transaction, will require us to obtain additional financing. Our access to capital funding is uncertain.

We expect to continue to incur significant development expenditures for our product candidates, and such expenditures will increase as a result of the Molecular Insight acquisition. We do not have committed external sources of funding for most of these projects. Our expenditures will be funded from cash on hand, or we may seek additional external funding for them, most likely through collaborative, license or royalty financing agreements with one or more pharmaceutical companies, equity securities issuances, debt financings, or government grants or contracts. To the extent we raise additional capital by issuing equity securities in the future, existing stockholders could experience substantial dilution in addition to the dilution experienced as a result of our recent equity offering and the Molecular Insight acquisition, and new investors could have rights superior to existing stockholders. Any debt financing that we are able to obtain may involve operating covenants that restrict our business and significant repayment obligations. To the extent that we raise additional funds through any new collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

We cannot predict when we will need additional funds, how much we will need, the form any financing may take or whether additional funds will be available at all, especially in light of current conditions in global credit and financial markets. Our need for future funding will depend on numerous factors, such as the availability of new product development projects; the achievement of events identified in our collaboration agreements that trigger payments to us from our collaboration partners, most of which are out of our control and rely entirely on the efforts of our partners; the progress and success of clinical trials and pre-clinical activities (including studies and manufacture of materials) of our product candidates conducted by our collaborators or us; the progress of research programs carried out by us; any changes in the breadth of our research and development programs; the progress of the research and development efforts of our collaborators; our ability to acquire or license other technologies or compounds that we seek to pursue; competing technological and market developments; the costs and timing of obtaining, enforcing and defending our patent and intellectual property rights; the costs and timing of regulatory approvals and filings by us and our collaborators; our ability to manage our growth; and any 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 we have acquired in the Molecular Insight transaction. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, 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 or may adversely affect our ability to operate as a going concern. We may not be able at the 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, the volume of which will increase as we continue research and development of candidates and programs acquired in the Molecular Insight transaction, 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.

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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 we have acquired in the Molecular Insight transaction. Pre-clinical studies and clinical trials are long, expensive and highly uncertain processes that can take many years. It will take us, or our collaborators, several years to complete clinical trials and the time required for completing testing and obtaining approvals is uncertain. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or our and our partners' financial constraints. The FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical trials, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. Results attained in early human clinical trials may not be indicative of results in later clinical trials. In addition, many of our investigational or experimental drugs are at an early stage of development, and successful commercialization of early stage product candidates requires significant research, development, testing and approvals by regulators, and additional investment. Our products in the research or pre-clinical development stage may not yield results that would permit or justify clinical testing. Our failure to demonstrate adequately the safety and efficacy of a product under development would delay or prevent marketing approval, which could adversely affect our operating results and credibility. The failure of one or more of our product candidates could have a material adverse effect on our business, financial condition and results of operations.

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 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 in the FDA's July 2012 Complete Response Letter or 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 subcutaneous and/or oral Relistor for chronic, non-cancer pain patients may be significantly delayed or terminated altogether.

Even if we agree to a path forward with Salix and the FDA, 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. 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.

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

We have limited experience in conducting clinical trials, and we rely on or obtain the assistance of others to design, conduct, supervise or monitor some or all aspects of some of our clinical trials, including our ongoing phase 2 trial of PSMA ADC. 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, significantly 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. other than Japan, where Ono has the responsibility for clinical trials. 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, 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, 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 such as those experienced worldwide over the last five years. 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.



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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 for castration-resistant prostate cancer, some of which are directed against PSMA, MIP-1404 and our other product candidates. 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 or any of our 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 or Ono may not be able to fulfill manufacturing obligations for Relistor, 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 (CMOs) for supply of Relistor active pharmaceutical ingredient (API) 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 Good Manufacturing Practices (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.

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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 cGMPs 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 obtain any required approval for their manufacturing facilities. 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 process 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 cGMPs and similar regulatory requirements. Failure of any manufacturer of Relistor or any of our product candidates to comply with applicable cGMPs 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.

We are dependent on patents and other intellectual property rights. The validity, enforceability and commercial value of these 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. 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 in relation to an issued patent that we own or license, we may not be able us to preclude competitors from commercializing drugs, and consequently such rights may not provide us with any meaningful competitive advantage. Patents also expire by law. For example, we and Salix have no patent protection outside the U.S. for subcutaneous Relistor, our approved product, although we do have regulatory data exclusivity which provides a competitive barrier to generic entry for limited periods of time. In the absence or upon expiration 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. 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. With respect to Japan, Ono has certain limited rights to prosecute, maintain and enforce relevant intellectual property. We may incur substantial costs in litigation seeking to uphold the validity of patents or to prevent infringement. If the outcome of litigation 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.



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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 Seattle Genetics. We can 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 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.

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, patentability of these pending patent applications and applicability of any of them to our programs are uncertain, if asserted against us, any related patent or other intellectual property rights could adversely affect our ability to commercialize our products.

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Research, development and commercialization of a biopharmaceutical often requires choosing between alternative development and optimization routes at various stages in the development process. Preferred routes 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 Ono and Salix for the commercialization and development of Relistor. We may not be able to maintain our relationships with them, 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 will be required to build the commercial infrastructure required to market, sell and support it. 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 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. Pursuant to our transition agreement with Wyeth Pharmaceuticals, Inc., we released Wyeth 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.



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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.

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

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. In the U.S., federal legislation has changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of legislation have decreased coverage and reimbursement. Though such legislation applies only to drug benefits for Medicare beneficiaries, private 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.

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We cannot rely on federal government grants and research contracts as a continuing source of funds.

Federal government grants and research contracts, in particular from the National Institutes of Health, have in the past generally been available for biotechnology research and development in various areas. Funds available under such grants or contracts, however, must be applied for, if awarded must be used to fund qualifying research and development programs specified in the application, and are subject to adjustment based on the results of periodic audits. The government's obligation to make payments under these grants and/or contracts is subject to appropriation by the U.S. Congress for funding in each year, which is subject to changes due to budgetary constraints, policy changes and other factors. While we have been awarded such grants and contracts in the past, we do not currently have significant funding from such sources, and in any event cannot rely on them as a continuing source of funds.

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.

Progenics has a history of operating losses, as does Molecular Insight, which has also been reorganized under the U.S. Bankruptcy Code.

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 reported an operating loss for 2012 and while we reported operating income for 2011, as a result of a one-time upfront 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, including those attendant to the product candidates and programs we have acquired in the Molecular Insight transaction. 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. Our operations may not be profitable even if any of our other product candidates under development are commercialized.

Molecular Insight has incurred net losses every year from its inception in 1997 and generated no significant revenue from product sales and only limited revenue from licenses. In December, 2010, Molecular Insight filed a voluntary petition in the United States Bankruptcy Court for the District of Massachusetts seeking relief under the provisions of Chapter 11 of the U.S. Bankruptcy Code (Case No. 10-23355). It operated its business and managed its properties as a

debtor in possession under bankruptcy protection until emerging from bankruptcy in May, 2011.

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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. In 2012, it varied between a high of \$11.34 and a low of \$1.41. 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, such as the FDA's July, 2012 Complete Response Letter with respect to the sNDA for Relistor subcutaneous injection for the treatment of OIC in adult patients with chronic, non-cancer pain; 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; purchases we may make under a share repurchase program, or discontinuation of any such purchases; and general market conditions. 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.

Sales of substantial numbers of shares of common stock, including sales by former Molecular Insight stockholders of unregistered Progenics shares they received in the acquisition, could 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, such as our 2012 follow-on underwritten public offering. We have in place a shelf registration statement which we accessed for that offering and which may be used for additional issuances of common stock, preferred stock, debt securities, warrants and other rights units to investors. We also have in place and utilize registration statements registering shares issuable pursuant to our equity compensation plans. Sales of our securities pursuant to these registration statements could cause the market price of our stock to decline. Any 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 2012 year end, our directors and executive officers together beneficially owned or controlled approximately nine percent of our outstanding common shares, and our five largest other stockholders over half. Should these parties choose to act 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 the 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.



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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, 2012.

Item 2. Properties

As of December 31, 2012, we occupy in total approximately 92,019 square feet of laboratory, manufacturing and office space on a single campus in Tarrytown, New York, under lease agreements expiring in December 2020. In addition to rents due under these arrangements, we are obligated to pay additional facilities charges, including utilities, taxes and operating expenses.

Item 3. Legal Proceedings

We are not a party to any material legal proceedings. From time to time we may be subject or a party to claims or legal proceedings arising in the ordinary course of business, none of which we currently believe will have a material adverse effect on our financial condition or results of operations.

Item 4. Not Applicable

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## PART II

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

## Price Range of Common Stock

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

	High	Low
2012: Fourth quarter	\$3.30	\$1.41
Third quarter	11.00	2.81
Second quarter	11.34	7.44
First quarter	10.50	8.32
2011: Fourth quarter	9.19	5.01
Third quarter	7.93	4.50
Second quarter	8.69	5.97
First quarter	6.50	5.32

On March 8, 2013, the last sale price for our common stock, as reported by The NASDAQ Stock Market LLC, was \$3.73. There were approximately 117 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 Stock Market (U.S.) Index and (ii) the NASDAQ Pharmaceutical Index, assuming an investment in each of \$100 on December 31, 2007.

## 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.



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## Item 6. Selected Financial Data

The selected financial data presented below as of December 31, 2012 and 2011 and for each of the three years in the period ended December 31, 2012 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, 2010, 2009 and 2008 and for each of the two years in the period ended December 31, 2009 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,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Royalty income	\$4,963	\$3,046	\$1,826	\$2,372	\$146
Collaboration revenue	8,525	76,764	1,413	44,351	59,885
Research grants and contract	488	4,810	4,573	1,968	7,460
Other revenues	72	176	140	256	180
Total revenues	14,048	84,796	7,952	48,947	67,671
Expenses:					
Research and development	31,840	53,183	50,640	49,798	82,290
License fees - research and development	1,170	578	1,270	1,058	2,830
Royalty expense	499	405	241	237	15
General and administrative	14,706	18,248	22,832	25,106	28,834
Depreciation and amortization	1,324	2,066	2,853	5,078	4,609
Total expenses	49,539	74,480	77,836	81,277	118,578
Operating (loss) income	(35,491)	10,316	(69,884)	(32,330)	(50,907)
Other income:					
Interest income	60	65	64	1,481	6,235
Gain on sale of marketable securities	-	-	-	237	-
Total other income	60	65	64	1,718	6,235
Net (loss) income before income taxes	(35,431)	10,381	(69,820)	(30,612)	(44,672)
Income tax benefit	-	-	95	-	-
Net (loss) income	\$(35,431)	\$10,381	\$(69,725)	\$(30,612)	\$(44,672)
Per share amounts on net (loss) income:					
Basic	\$(1.02 )	\$0.31	\$(2.14 )	\$(0.98 )	\$(1.48 )
Diluted	\$(1.02 )	\$0.31	\$(2.14 )	\$(0.98 )	\$(1.48 )

	December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$58,838	\$70,105	\$47,918	\$90,903	\$56,186
Auction Rate and marketable securities	3,240	3,332	3,608	5,293	85,188
Working capital	58,805	65,890	42,207	95,388	85,983
Total assets	76,308	80,110	62,738	113,613	157,833
Deferred revenue - current	838	204	-	-	-
Deferred revenue - long term	-	162	-	-	-

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Other liabilities - long term	1,078	1,497	1,635	-	266
Total stockholders' equity	66,568	71,801	51,308	107,607	119,369

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

Overview

General. Progenics Pharmaceuticals develops innovative medicines for oncology. As discussed in Business, above, a significant part of our research and development efforts centers on prostate specific membrane antigen (PSMA), where we are conducting phase 2 clinical trials of two product candidates for prostate cancer: our therapeutic candidate, PSMA ADC, and MIP-1404, an imaging agent candidate in development by our Molecular Insight Pharmaceuticals subsidiary. Among other assets in our pipeline of targeted radiotherapy and molecular imaging compounds are a group of small molecule therapeutics, MIP-1095, -1555 and -1558, in preclinical study for metastatic prostate cancer and other PSMA-expressing cancers, and Azedra, an ultra-orphan radiotherapy candidate in phase 2 study, for pheochromocytoma and potential additional indications. For the acquisition of the privately-held Molecular Insight, we issued its then-stockholders a total of 4.6 million shares of Progenics common stock in an unregistered transaction pursuant to SEC Regulation D, and agreed to pay potential milestones, in cash or Progenics stock at Progenics' 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 all Molecular Insight products. As noted below, Molecular Insight is not included in the discussion and analysis in this Item 7.

Progenics has developed internally and acquired from research institutions, pharmaceutical and biotechnology companies compounds and technologies which we determine to advance with other parties, including our first commercial drug, Relistor® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation, which as discussed in Business, above, we have licensed to Salix Pharmaceuticals worldwide other than Japan, where we have licensed the subcutaneous formulation of the drug to Ono Pharmaceutical. We have also recently out-licensed to MedImmune our proprietary C. difficile research program for a \$5.0 million upfront payment (received in 2013) and the right to receive potential future milestone and royalty payments, and transferred our PRO 140 HIV viral-entry inhibitor to CytoDyn for \$3.5 million cash and the right to receive potential future payments as well. We have recently suspended investment in our proprietary phosphoinositide 3-kinase (PI3K) inhibitor research and are evaluating alternative paths forward for this program. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving our 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 upfront, commercialization milestone, royalty 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 the actions of Salix and Ono, decisions by the FDA and other regulatory bodies, such as the Complete Response Letter mentioned in Business and Risk Factors, the outcome of clinical and other testing of Relistor, and, to the extent requested by our collaboration partners, our own efforts.

In late 2012, we completed an underwritten public offering of 12,650,000 shares of common stock at a public offering price of \$2.00 per share, resulting in net proceeds of approximately \$23.3 million.

Our sources of revenues for the year 2012 have primarily consisted of payments under out-licensing and collaboration agreements and royalties. To date, product sales have consisted solely of limited revenues from the sale of research reagents, which we expect will not significantly increase over current levels in the near future.

A majority of our expenditures to date have been for research and development activities. During 2012, expenses for Oncology, primarily related to PSMA ADC, were \$29.1 million compared to \$22.2 million in 2011 and \$17.4 million in 2010. Expenses for Relistor and Other programs in 2012 were \$1.7 million and \$2.7 million, respectively,

compared to \$23.2 million and \$8.8 million in 2011 and \$23.4 million and \$11.4 million in 2010. We also expect to incur a significant amount of development expenses for our PSMA ADC product candidate as clinical trials progress and additional development expenses for MIP assets, while expenses, including reimbursement revenue, related to Relistor depend on the amount of research and development work we perform upon request by Salix or Ono.

At December 31, 2012, we held \$58.8 million in cash and cash equivalents, a decrease of \$11.3 million from \$70.1 million at 2011 year-end. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We may require additional funding in the future, and if we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend our remaining operations. We expect to incur operating losses during the near term. At December 31, 2012, cash, cash equivalents and auction rate securities decreased \$11.3 million to \$62.1 million from \$73.4 million at 2011 year-end.

Our discussion and analysis in this Item 7 does not include assets, liabilities, revenue, expense, income, loss, commitments, contingencies or other items or matters relating to Molecular Insight, which we acquired subsequent to the periods covered by this item. See also Note 15 to our financial statements.

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

	2012	2011	2010	2012 vs. 2011 Percent Change	2011 vs. 2010
Revenues	\$14,048	\$84,796	\$7,952	(83 %)	966 %
Expenses	(49,539)	(74,480)	(77,836)	(33 %)	(4 %)
Operating (loss) income	(35,491)	10,316	(69,884)	(444%)	(115 %)
Other income	60	65	64	(8 %)	2 %
Income tax benefit	-	-	95	N/ A	(100 %)
Net (loss) income	\$(35,431)	\$10,381	\$(69,725)	(441%)	(115 %)

## Revenues:

Our sources of revenue during 2012, 2011 and 2010, included our License Agreements with Salix and Ono, payments from a former collaborator, agreements relating to out-licensing of assets, research grants from the National Institutes of Health (NIH) and, to a small extent, sales of research reagents.

Sources of Revenue	2012	2011	2010	2012 vs. 2011 Percent Change	2011 vs. 2010
Royalty income	\$4,963	\$3,046	\$1,826	63 %	67 %
Collaboration revenue	8,525	76,764	1,413	(89%)	5,333 %
Research grants	488	4,810	4,573	(90%)	5 %
Other revenues	72	176	140	(59%)	26 %
Total	\$14,048	\$84,796	\$7,952	(83%)	966 %

Royalty income. We began earning royalties from net sales of subcutaneous Relistor by our former collaborator Wyeth (now a Pfizer Inc. subsidiary) in June 2008. Under a 2009 transition agreement, Wyeth continued to distribute Relistor in the U.S. until April 1, 2011, in Europe until October 1, 2011, and in Australia until December 1, 2011, at which times Salix assumed those responsibilities. Beginning in the fourth quarter of 2010, no royalties were payable to us on the net sales of Relistor by Wyeth.

During 2012, 2011 and 2010, we recognized \$4,963, \$3,046 and \$1,826, respectively, of royalty income based on net sales of Relistor reported by Salix or Wyeth.

	Relistor Net Sales Reported by Collaborators Years Ended December 31,		
	2012	2011	2010
U.S.	\$29,200	\$21,500	\$9,500
Ex-U.S.	4,000	5,500	6,600

Global \$33,200 \$27,000 \$16,100

Collaboration revenue:

During 2012, we recognized \$7,949 of revenue from upfront and reimbursement payments from partnering our PRO 140 and C. difficile programs. As of December 31, 2012, \$676 is recorded in deferred revenue – current.

During 2012 and 2011, we recognized \$558 and \$75,091, respectively, of revenue from Salix, which includes \$204 and \$59,634, respectively, from the \$60,000 upfront cash payment under our License Agreement, \$225 in 2011 in respect of Salix ex-U.S. sublicensee revenue and \$354 and \$15,232, respectively, as reimbursement of our expenses, in accordance with the License Agreement. As of December 31, 2012, \$162 is recorded in deferred revenue – current. During 2011 and 2010, we recognized \$1,630 and \$1,383, respectively, of revenue from Wyeth, as reimbursement of expenses under our transition agreement. We received no such reimbursement in 2012.

During 2012, 2011 and 2010, we recognized \$18, \$43 and \$30, respectively, of reimbursement revenue for activities requested by Ono.

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Research grants. During 2012 and 2011, we recognized \$488 and \$4,810, respectively, as revenue from federal government grants by the NIH to support research and development programs. The decrease in grant revenue resulted from lower reimbursable expenses in 2012 than in 2011. NIH grant revenue increased from 2010 to 2011, from \$4,573 to \$4,810, as a result of new grant awards and higher reimbursable expenses in 2011 than in 2010. We expect NIH reimbursable expenses to continue to decline from the 2012 level.

Other revenues, primarily from orders for research reagents, decreased to \$72 for 2012 from \$176 for 2011 and \$140 for 2010.

## Expenses:

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 \$33,509 for 2012 from \$54,166 for 2011, and from \$52,151 for 2010. During 2012, the decrease in research and development expenses compared to those in 2011 was primarily due to lower (i) clinical trial costs from activities related to oral methylnaltrexone phase 3 study and regulatory filing fees for the submission of the sNDA for subcutaneous Relistor, (ii) purchases of manufacturing supplies on behalf of Salix, (iii) compensation expense and (iv) rent expense, partially offset by higher license fee and clinical trial expenses related to PSMA ADC. See Liquidity and Capital Resources – Uses of Cash, for details of the changes in these expenses by project. Primarily in 2011, Salix reimbursed us for development expenses we incurred related to Relistor. Portions of our expenses are funded through grants from the NIH (see Revenues- Research Grants). Company-wide headcount as of December 31, 2012 declined to 76 from 105 as of December 31, 2011 and 159 as of December 31, 2010. The changes in research and development expense, by category of expense, are as follows:

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010	Percent change
Salaries and benefits	\$15,372	\$18,658	\$18,469	(18%)	1	%

2012 vs. 2011 Salaries and benefits decreased due to a decline in average headcount to 62 from 104 in the research and development departments (see below for decline in average general and administrative headcount) and lower accrued bonus expense in 2012, partially offset by an increase in expenses of \$1,804 incurred in the first quarter of 2012 in connection with a former senior executive retirement and accrued severance expense related to the additional headcount reductions in the third quarter.

2011 vs. 2010 Salaries and benefits increased due to accrued severance expenses related to headcount reduction and higher accrued bonus expense, partially offset by a decrease in salary expenses due to a decline in average headcount to 104 from 138 for 2011 and 2010, respectively, in the research and development departments.

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010	Percent change
Share-based compensation	\$4,568	\$4,499	\$5,091	2%	(12	%)

2012 vs. 2011 Share-based compensation increased for 2012 compared to 2011 primarily due to the acceleration of options and restricted stock expenses of \$1,638 resulting from a former senior executive retirement, partially offset by lower restricted stock expenses and no employee stock purchase plan expenses resulting from the 2011 termination of those plans.

2011 vs. 2010 Share-based compensation decreased for 2011 compared to 2010 due to lower restricted stock and employee stock purchase plan expenses, partially offset by an increase in stock option plan expenses.

For 2011, share-based compensation included restricted stock and option plan expenses from (i) accelerated vesting of outstanding awards to non-management employees in connection with a change in program eligibility and termination of the Company's employee stock purchase plans (the latter of which resulted in a decline in share-based compensation), and (ii) a shift in headcount from general and administrative departments to research and development. See Critical Accounting Policies – Share-Based Payment Arrangements.

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	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Clinical trial costs	\$2,692	\$10,099	\$7,056	(73%)	43 %

2012 vs. 2011 Clinical trial costs decreased primarily due to (i) Relistor (\$9,132), resulting from lower clinical trial activities related to oral methylnaltrexone study, partially offset by increased expenses in Oncology (\$1,700), primarily related to PSMA ADC and Other (\$25).

2011 vs. 2010 Clinical trial costs increased primarily due to higher expenses for (i) Relistor (\$3,385), from increased clinical trial expenses including activities related to oral methylnaltrexone phase 3 study and regulatory filing fees for the submission of the sNDA for subcutaneous Relistor and (ii) Oncology (\$316), partially offset by decreased expenses for Other programs (\$658).

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Laboratory and manufacturing supplies	\$592	\$4,203	\$2,388	(86%)	76 %

2012 vs. 2011 Laboratory and manufacturing supplies decreased due to lower expenses in (i) Relistor (\$2,197), (ii) Oncology (\$388), resulting from a decline in manufacturing supplies for PSMA ADC, and (iii) Other (\$1,026).

2011 vs. 2010 Laboratory and manufacturing supplies increased due to higher expenses for (i) Relistor (\$1,562), primarily due to purchases of manufacturing supplies on behalf of Salix, and (ii) Oncology (\$375), resulting from increase in expenses for PSMA ADC, partially offset by lower expenses for Other programs (\$122).

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Contract manufacturing and subcontractors	\$3,111	\$6,713	\$6,853	(54%)	(2 %)

2012 vs. 2011 Contract manufacturing and subcontractors decreased due to lower expenses for Relistor (\$2,399), resulting from a decrease in purchases of subcutaneous Relistor related products, and Other (\$1,596), partially offset by an increase in Oncology (\$393).

2011 vs. 2010 Contract manufacturing and subcontractors decreased due to lower expenses for (i) Oncology (\$83), resulting from a decline in manufacturing expenses for PSMA ADC, (ii) Relistor (\$2), due to lower contract manufacturing expenses for the multi-dose pen, and (iii) Other (\$55).

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.

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
Consultants	\$330	\$1,270	\$3,310	(74%)	(62%)

2012 vs. 2011 Consultants expense decreased due to lower expenses in 2012 for Relistor (\$816), primarily related to the sNDA submission for subcutaneous Relistor in non-cancer pain patients, Oncology (\$18) and Other programs (\$106).

2011 vs. 2010 Consultants expenses decreased due to lower expenses for Relistor (\$2,082) and Other programs (\$41), partially offset by an increase in Oncology (\$83).

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.

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
License fees	\$1,170	\$578	\$1,270	102%	(54%)

2012 vs. 2011 License fees increased due to higher expenses for Oncology (\$902), due to the initiation of a phase 2 trial, partially offset by lower expenses for Relistor (\$156) and Other programs (\$154).

2011 vs. 2010 License fees decreased primarily due to lower expenses for Other programs (\$663), Relistor (\$27) and Oncology (\$2).

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	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Royalty expense	\$499	\$405	\$241	23%	68 %

2012 vs. 2011 The increase in royalty expense is due to higher net sales of Relistor in 2012.

2011 vs. 2010 The increase in royalty expense is due to higher net sales of Relistor in 2011.

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Other operating expenses	\$5,175	\$7,741	\$7,473	(33%)	4 %

2012 vs. 2011 Other operating expenses decreased primarily due to decreases in rent (\$1,943), travel (\$111), insurance (\$55) and other operating expenses (\$489), partially offset by increases in expenses for facilities (\$32).

2011 vs. 2010 Other operating expenses increased primarily due to higher expenses for rent (\$237), insurance (\$89) and travel (\$20), partially offset by a decrease in expenses for facilities (\$78).

General and Administrative Expenses decreased to \$14,706 for 2012 from \$18,248 for 2011 and from \$22,832 for 2010, as follows:

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Salaries and benefits	\$6,493	\$7,228	\$8,086	(10%)	(11 %)

2012 vs. 2011 Salaries and benefits decreased due to a decline in average headcount to 24 from 32, in the general and administrative departments and lower accrued bonus expense in 2012, partially offset by an increase in accrued severance expense related to additional headcount reductions in the third quarter.

2011 vs. 2010 Salaries and benefits decreased due to a decline in average headcount to 32 from 39, in the general and administrative departments (see above for decline in average research and development headcount), and lower accrued bonus expense, partially offset by accrued severance expenses related to headcount reduction.

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Share-based compensation	\$1,968	\$1,863	\$4,424	6%	(58 %)

2012 vs. 2011 Share-based compensation increased due to higher stock option expenses in connection with the third quarter 2012 restructuring, partially offset by lower restricted stock and elimination of employee stock purchase plans expenses as a result of their termination in 2011.

2011 vs. 2010 Share-based compensation decreased due to lower restricted stock, stock option and employee stock purchase plans expenses.

For 2011, share-based compensation reflected accelerated vesting in connection with termination of our employee stock purchase plans, as described under research and development expenses, above.

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Consulting and professional fees	\$2,362	\$4,389	\$5,843	(46%)	(25 %)

2012 vs. 2011 Consulting and professional fees decreased due to lower consulting (\$1,246), audit (\$297), patent (\$294), accounting (\$91), legal (\$63) and other fees (\$36).

2011 vs. 2010 Consulting and professional fees decreased due to lower patent (\$1,203), legal (\$497) and other fees (\$13), which were partially offset by an increase in consulting (\$137), tax accounting (\$63) and audit fees (\$59).

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Other operating expenses	\$3,883	\$4,768	\$4,479	(19%)	6 %

2012 vs. 2011 Other operating expenses decreased due to lower expenses for rent (\$646), investor relations (\$63), taxes (\$30), and other operating expenses (\$359), partially offset by an increases in recruiting (\$137), computer software (\$66) and travel (\$10).

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2011 vs. 2010 Other operating expenses increased due to higher expenses for rent (\$82), taxes (\$59), computer software (\$87) and other operating expenses (\$122), partially offset by decreases in recruiting (\$51) and travel (\$10).

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Depreciation and amortization	\$ 1,324	\$ 2,066	\$ 2,853	(36%)	(28 %)

2012 vs. 2011 Depreciation and amortization expense decreased to \$1,324 for 2012 from \$2,066 for 2011, primarily due to lower machinery and equipment fixed asset balances.

2011 vs. 2010 Depreciation and amortization expense decreased to \$2,066 for 2011 from \$2,853 for 2010, primarily due to lower leasehold improvement amortization expenses.

Other income:

	2012	2011	2010	2012 vs. 2011	2011 vs. 2010
				Percent change	
Interest income	\$ 60	\$ 65	\$ 64	(8%)	2 %

2012 vs. 2011 Interest income decreased to \$60 for 2012 from \$65 for 2011.

2011 vs. 2010 Interest income increased to \$65 for 2011 from \$64 for 2010. For 2011 and 2010, investment income remained unchanged at \$65, while amortization of premiums, net of discounts, was \$0 and (\$1) for years ended December 31, 2011 and 2010, respectively.

Interest income, as reported, is primarily the result of investment income from our auction rate securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those securities.

Income Taxes:

For 2012 and 2010, our pre-tax loss was \$35,431 and \$69,820. For 2011 we recognized \$10,381 in pre-tax income primarily as a result of the \$60,000 Salix upfront cash payment, which has been offset fully with net operating loss carry-forwards. We received a federal tax refund of \$95 in 2010 from new legislation permitting the carryback of NOLs to 2005 as well as permitting the suspension of limitations on alternative minimum tax NOL utilization.

Net Income (Loss):

2012 net loss was \$35,431, compared to net income of \$10,381 for 2011 and net loss of \$69,725 for 2010.

Liquidity and Capital Resources

We have to date funded operations principally through payments received from private placements of equity securities, public offerings of common stock, collaborations, grants and contracts, royalties, interest on investments, proceeds from the exercise of outstanding options and warrants, and through September 30, 2011, sales of our common stock under our two employee stock purchase plans (Purchase Plans) which were terminated during 2011.

We received in 2012 a \$3,500 payment upon sale of our PRO 140 program and are eligible to receive future milestone and royalty payments in respect of this asset.

Under the Salix License Agreement, we received in 2011 a \$60,000 upfront cash payment and \$225 in respect of Salix ex-U.S. sublicensee revenue and are eligible to receive development and commercialization milestone payments plus royalties on net sales and 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Salix receives from ex-U.S. sublicensees.

Our expenses and reimbursement revenue related to Relistor have declined substantially since Salix assumed direct responsibility for expenses under third-party contracts we have assigned to it. Under the Salix License Agreement, we are reimbursed for Salix approved full-time equivalents (FTE) and third-party development expenses incurred and paid by us after February 3, 2011.

At December 31, 2012, we held \$58,838 in cash and cash equivalents, a decrease of \$11,267 from \$70,105 at December 31, 2011. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. In addition, at December 31, 2012 and 2011, our investment in auction rate securities classified as long-term assets on the Consolidated Balance Sheets amounted to \$3,240 and \$3,332, respectively.

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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 reduce headcount and other overhead expenses.

Cash used in operating activities for 2012 and 2010 was \$34,644 and \$46,410, 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. Our cash flow from operating activities was positive for 2011, due to the receipt of a \$60,000 Salix upfront payment, \$225 in respect of Salix ex-U.S. sublicensee revenue and \$16,289 in reimbursement payments from Salix and Wyeth, partially offset by expenditures on our research and development programs and general and administrative costs. See Risk Factors.

During the third quarter of 2011, we put in place a shelf registration statement with the SEC which may be used for the issuance of up to \$100.0 million of common stock, preferred stock, debt securities, warrants, other rights and units. In December 2012, we completed a public offering of 12.7 million shares of common stock, and received net proceeds of approximately \$23.3 million.

### Sources of Cash

**Operating Activities.** 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 the License Agreement with Ono. During 2011 we received \$79,998 under our collaborations, consisting of (i) \$60,000 Salix upfront cash payment and \$225 in respect of Salix ex-U.S. sublicensee revenue (ii) \$14,659 in reimbursement payments under the Salix License Agreement, (iii) \$1,767 in royalties from Salix, (iv) \$3,317 under the Transition Agreement with Wyeth and (v) \$30 under the License Agreement with Ono. During 2010 we received \$10,351 from Wyeth, consisting of (i) \$0 as reimbursements payments under the 2005 Wyeth collaboration, (ii) \$7,906 under the Transition Agreement, (iii) \$2,415 in royalties and (iv) \$30 under the License Agreement with Ono.

We have partially funded research programs through awards from the NIH. For 2012, 2011 and 2010, we received \$576, \$5,178 and \$4,315, respectively, of revenue from all of our NIH awards. We expect a further decline in NIH reimbursable expenses.

Changes in Accounts receivable and Accounts payable for 2012, 2011 and 2010 resulted from the timing of receipts from Salix, Wyeth, Ono, other partnering transactions, and NIH, and payments made to trade vendors in the normal course of business.

Other than potential amounts we may receive from partnering transactions, we have no other external sources of capital. Other than revenues from Relistor, we expect no significant product revenues for a number of years, as it will take at least that much time, if ever, to bring our product candidates to the commercial marketing stage.

**Investing Activities.** Of \$58,838 in cash and cash equivalents primarily invested in money market funds of which, at December 31, 2012, \$51,127 is guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee program. Our auction rate securities of \$3,240 include \$2,300 of securities collateralized by student loan obligations subsidized by the U.S. government, \$100 of which was redeemed at par during the first quarter of 2012. These investments, while rated investment grade by the Standard & Poor's and Moody's rating agencies and predominantly having scheduled maturities greater than ten years, are heavily concentrated in the U.S. financial sector. During 2012, proceeds from sales of fixed assets were \$390.

Financing Activities. During 2012, net cash provided by financing activities includes \$23,348 in net proceeds that we received for the issuance of approximately 12.7 million shares of our common stock. In addition, during 2012, 2011 and 2010, we received cash of \$306, \$3,726 and \$3,896, respectively, from sales of common stock in satisfaction of severance obligations (in 2012) and under the now-discontinued employee stock purchase plans (in 2011) and exercise of stock options. The amount of cash we receive from these sources fluctuates commensurate with headcount levels and changes in the price of our common stock on the grant date for options exercised, and on the sale date for shares sold under the now-terminated employee stock purchase plans.

Unless we obtain regulatory approval from the FDA for additional product candidates and/or enter into agreements with corporate collaborators with respect to our additional technologies, we will be required to fund our operations in the future through sales of common stock or other securities, royalty or other financing agreements and/or grants and government contracts. 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.



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## Uses of Cash

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. Our expenses for research and development for 2012, 2011 and 2010, were \$33,509, \$54,166 and \$52,151, respectively. Included in the 2012 period 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.

For 2012, 2011 and 2010, research and development costs incurred, by project, were as follows:

	2012	2011	2010
Oncology	\$29.1	\$22.2	\$17.4
Relistor	1.7	23.2	23.4
Other programs	2.7	8.8	11.4
Total	\$33.5	\$54.2	\$52.2

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

Investing Activities. During 2012, 2011 and 2010, we have spent \$767, \$226 and \$2,171, 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 and collaboration agreements, including those to which our Molecular Insight subsidiary is a party. The following table summarizes our contractual obligations as of December 31, 2012 for future payments under our agreements, and does not include MIP obligations:

	Payments due by Year-end				
	Total (in millions)	2013	2014-2015	2016-2017	Thereafter
Operating leases	\$20.6	\$2.4	\$4.9	\$5.1	\$ 8.2
License, collaboration and other agreements:					
Fixed payments	0.5	-	0.2	0.3	-
Contingent payments (1)	72.1	-	2.3	3.0	66.8
Total	\$93.2	\$2.4	\$7.4	\$8.4	\$ 75.0

(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.

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### 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 Annual Report on Form 10-K for 2012. 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. On an ongoing basis, we evaluate our estimates. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our evaluation 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, these estimates and assumptions are subject to a number of factors and uncertainties regarding their ultimate outcome and, therefore, actual results could differ from these estimates.

We have identified our critical accounting policies and estimates 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.

In October 2009, the FASB updated ASC 605 Revenue Recognition by specifying how to separate deliverables in multiple-deliverable arrangements, and how to measure and allocate arrangement consideration to one or more units of accounting. Under ASC 605, the delivered item(s) are separate units of accounting, provided (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. We adopted this update on January 1, 2011.

Royalty revenue is recognized based upon net sales of related licensed products. Royalty revenue is recognized in the period the sales 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.

Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term deferred revenue. The estimate of the classification of deferred revenue as short-term or long-term is based upon the periods in which we expect to perform joint committee services and/or non-reimbursable technical assistance.

**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.

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) zero expected dividend yield 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 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.

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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 and consultants are calculated separately from stock options granted to employees and other officers.

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 the fair value of the non-qualified stock option awards 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 the resulting compensation expense recognized in future periods as compared to prior periods.

For performance-based stock option awards vesting of a defined portion of each award will occur earlier if a defined performance condition is achieved; more than one condition may be achieved in any period. We estimate the probability of achievement of each performance condition and use those probabilities to determine the requisite service period of each award. The requisite service period for the award is the shortest of the explicit or implied service periods. For performance and market-based stock option awards to our CEO (consisting of options in 2010), vesting occurs on the basis of the achievement of specified performance or market-based milestones. The options have an exercise price equal to the closing price on our common stock on the date of grant. The awards are valued using a Monte Carlo simulation model and the expense related to these grants will be recognized over the shortest estimated time for the achievement of the performance or market conditions. On July 1, 2011, we granted an option to our CEO which vests on the basis of the achievement of specified performance-based milestones. The option has an exercise price equal to the closing price of our common stock on the date of grant. The award is valued using the Black-Scholes option pricing model and the expense related to this grant will be recognized during the period in which one of the performance milestones is achieved. The awards will not vest unless one of the performance milestones is achieved or the market condition is met. Changes in the estimate of probability of achievement of any performance or market condition will be reflected in compensation expense of the period of change and future periods affected by the change.

**Research and Development Expenses Including Clinical Trial Expenses.** Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our 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 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 approximates 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.** Our available-for-sale investment portfolio consists of money market funds and auction rate securities, 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 continue to monitor markets for our investments and consider the impact, if any, of market conditions on the fair market value of our investments.

We expect to recover the amortized cost of all of our investments at maturity. Currently, we do not anticipate having to sell these securities in order to operate our business and we believe that it is not more likely than not that we will be required to sell these securities before recovery of principal. We do not believe the carrying values of our investments are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

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 hold is 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.

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### Impact of Recently Issued Accounting Standards

In June 2011, the FASB issued ASU No. 2011-05, which requires that comprehensive income and the related components be presented in a single continuous statement or in two separate but consecutive statements. The ASU was effective beginning January 1, 2012. We adopted this new standard, presenting comprehensive income in two separate but consecutive statements, and applied it retrospectively on January 1, 2012. As this guidance relates to presentation only, the adoption of this standard had no material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is the result of joint efforts by the FASB and International Accounting Standards Board to develop a single, converged fair value framework. The converged guidance specifies how to measure fair value and what disclosures to provide about fair value measurements. The ASU is effective for interim and annual periods beginning after December 15, 2011. We adopted this new standard on January 1, 2012 and it had no material impact on our consolidated financial statements.

In February 2013, The FASB issued ASU No. 2013-02, which requires presentation of amounts reclassified out of accumulated other comprehensive income by component. The ASU is effective for reporting periods beginning after December 15, 2012. We are currently evaluating the effect this ASU will have on our consolidated financial statements.

### Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our primary investment objective is to preserve principal. Our money market funds and auction rate securities have interest rates that were variable and totaled \$59,464 at December 31, 2012. As a result, we do not believe that these investment balances have a material exposure to interest-rate risk.

At December 31, 2012, we continue to hold approximately \$3,240 (5.4% of assets measured at fair value) of auction rate securities, in respect of which we have received all scheduled interest payments. The principal amount of these remaining auction rate securities will not be accessible until the issuer calls or restructures the underlying security, the underlying security matures and is paid or a buyer outside the auction process emerges.

We continue to monitor the market for auction rate securities and consider the impact, if any, of market conditions on the fair market value of our investments. We believe that the failed auctions experienced to date are not a result of the deterioration of the underlying credit quality of these securities, although valuation of them 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. We do not believe the carrying values of these auction rate securities are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

The valuation of the auction rate securities we hold is 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. We re-evaluated the valuation of these securities as of December 31, 2012 and the temporary impairment amount decreased \$8 from \$268 at December 31, 2011 to \$260. A 100 basis point increase to our internal analysis would result in a \$35 increase in the temporary impairment of these securities as of December 31, 2012.

### 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 Chief Executive Officer (CEO) and Treasurer, 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.

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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 Treasurer, 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 Treasurer 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, 2012 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 principal executive and principal financial officers 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 and it includes policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our 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 our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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, 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, 2012. 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, 2012 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, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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.

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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, 2012, 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, 2012 and the related consolidated statement of income and comprehensive income, stockholders' equity, and cash flows for the year ended December 31, 2012 of Progenics Pharmaceuticals Inc. and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut  
March 15, 2013

Item 9B. Other Information

None.

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PART III

The information required by the Form 10-K Items listed in the following table will be included under the respective headings specified for such Items in our definitive proxy statement for our 2013 Annual Meeting of Stockholders to be filed with the SEC:

Item of Form 10-K	Location in 2013 Proxy Statement
Item 10. Directors, Executive Officers and Corporate Governance	Election of Directors. Board and Committee Meetings. Executive Officers of the Company. Section 16(a) Beneficial Ownership Reporting and Compliance. Code of Business Ethics and Conduct.* *The full text of our code of business ethics and conduct is available on our website ( <a href="http://www.progenics.com/documents.cfm">http://www.progenics.com/documents.cfm</a> ).
Item 11. Executive Compensation	Executive Compensation. Compensation Committee Report. Compensation Committee Interlocks and Insider Participation.
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	Equity Compensation Plan Information. Security Ownership of Certain Beneficial Owners and Management.
Item 13. Certain Relationships and Related Transactions, and Director Independence	Certain Relationships and Related Transactions. Affirmative Determinations Regarding Director Independence and Other Matters.
Item 14. Principal Accounting Fees and Services	Fees Billed for Services Rendered by our Independent Registered Public Accounting Firm. Pre-approval of Audit and Non-Audit Services by the Audit Committee.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

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

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

Consolidated Financial Statements of Progenics Pharmaceuticals, Inc.:

Reports of Independent Registered Public Accounting Firms

Consolidated Balance Sheets at December 31, 2012 and 2011

Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010

Notes to Consolidated Financial Statements

(b) Financial Statement Schedules

All financial statement schedules referred to in Item 12-01 of Regulation S-X 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.

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<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010</u>	F-6
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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 sheet of Progenics Pharmaceuticals Inc. as of December 31, 2012, and the related consolidated statement of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 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 audit provides 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, 2012, and the consolidated results of its operations and its cash flows for the year ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Progenics Pharmaceuticals Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP  
Hartford, Connecticut  
March 15, 2013

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the consolidated balance sheet as of December 31, 2011 and the related consolidated statements of operations and comprehensive income (loss), of stockholders' equity and of cash flows for each of the two years in the period ended December 31, 2011 present fairly, in all material respects, the financial position of Progenics Pharmaceuticals, Inc. and its subsidiaries at December 31, 2011, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 audits 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
New York, New York  
March 15, 2012  
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## PROGENICS PHARMACEUTICALS, INC.

## CONSOLIDATED BALANCE SHEETS

(amounts in thousands, except for par value and share amounts)

	December 31,	
	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$58,838	\$70,105
Accounts receivable	6,937	1,516
Other current assets	1,692	919
Total current assets	67,467	72,540
Auction rate securities	3,240	3,332
Fixed assets, at cost, net of accumulated depreciation and amortization	3,399	4,038
Deferred tax assets – long term	2,052	-
Other assets	150	200
Total assets	\$76,308	\$80,110
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$5,640	\$6,331
Deferred tax liability - current	2,069	-
Deferred revenue - current	838	204
Other current liabilities	115	115
Total current liabilities	8,662	6,650
Deferred revenue - long term	-	162
Other liabilities	1,078	1,497
Total liabilities	9,740	8,309
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; 80,000,000 shares authorized; issued – 46,765,472 in 2012 and 34,046,409 in 2011	61	44
Additional paid-in capital	493,613	463,440
Accumulated deficit	(424,105)	(388,674)
Accumulated other comprehensive loss	(260 )	(268 )
Treasury stock, at cost (200,000 shares in 2012 and 2011)	(2,741 )	(2,741 )
Total stockholders' equity	66,568	71,801
Total liabilities and stockholders' equity	\$76,308	\$80,110

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

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## PROGENICS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(amounts in thousands, except net (loss) income per share)

	Years Ended December 31,		
	2012	2011	2010
Revenues:			
Royalty income	\$4,963	\$3,046	\$1,826
Collaboration revenue	8,525	76,764	1,413
Research grants	488	4,810	4,573
Other revenues	72	176	140
Total revenues	14,048	84,796	7,952
Expenses:			
Research and development	31,840	53,183	50,640
License fees – research and development	1,170	578	1,270
Royalty expense	499	405	241
General and administrative	14,706	18,248	22,832
Depreciation and amortization	1,324	2,066	2,853
Total expenses	49,539	74,480	77,836
Operating (loss) income	(35,491)	10,316	(69,884)
Other income:			
Interest income	60	65	64
Total other income	60	65	64
Net (loss) income before income taxes	(35,431)	10,381	(69,820)
Income tax benefit	-	-	95
Net (loss) income	\$(35,431)	\$10,381	\$(69,725)
Net (loss) income per share - basic	\$(1.02 )	\$0.31	\$(2.14 )
Weighted-average shares - basic	34,754	33,375	32,590
Net (loss) income per share - diluted	\$(1.02 )	\$0.31	\$(2.14 )
Weighted-average shares - diluted	34,754	33,494	32,590

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

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PROGENICS PHARMACEUTICALS, INC.

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

	Years Ended December 31,		
	2012	2011	2010
Net (loss) income	\$(35,431)	\$10,381	\$(69,725)
Other comprehensive income:			
Net change in unrealized loss on auction rate securities	8	24	15
Total other comprehensive income	8	24	15
Comprehensive (loss) income	\$(35,423)	\$10,405	\$(69,710)

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

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## PROGENICS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2012, 2011 and 2010

(amounts in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
Balance at December 31, 2009	32,142	\$ 42	\$ 439,943	\$ (329,330 )	\$ (307 )	(200)	\$(2,741)	\$ 107,607
Net loss	-	-	-	(69,725 )	-	-	-	(69,725 )
Other comprehensive income	-	-	-	-	15	-	-	15
Compensation expenses for share-based payment arrangements	-	-	9,515	-	-	-	-	9,515
Issuance of restricted stock, net of forfeitures	173	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	1,011	1	3,895	-	-	-	-	3,896
Balance at December 31, 2010	33,326	43	453,353	(399,055 )	(292 )	(200)	(2,741)	51,308
Net income	-	-	-	10,381	-	-	-	10,381
Other comprehensive income	-	-	-	-	24	-	-	24
Compensation expenses for share-based payment arrangements	-	-	6,362	-	-	-	-	6,362
Forfeitures of restricted stock	(38 )	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	758	1	3,725	-	-	-	-	3,726
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	-	-	-	-	23,348
Forfeitures of restricted stock	(6 )	-	-	-	-	-	-	-
Sale of common stock under stock incentive plan and	75	-	306	-	-	-	-	306

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exercise of stock options

Balance at December 31, 2012 46,765 \$ 61 \$ 493,613 \$ (424,105 ) \$ (260 ) (200) \$(2,741) \$66,568

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

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## PROGENICS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)

	Years Ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net (loss) income	\$(35,431)	\$10,381	\$(69,725)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	1,324	2,066	2,853
Gains on sales of fixed assets	(327 )	-	-
Expenses for share-based compensation awards	6,536	6,362	9,515
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(5,421 )	767	5,239
(Increase) decrease in other current assets	(754 )	882	(333 )
(Increase) decrease in deferred tax and other assets	(2,002 )	1,050	617
(Decrease) increase in accounts payable and accrued expenses	(691 )	(3,352 )	3,847
Increase in deferred revenue – current	634	204	-
Increase (decrease) in deferred tax and other current liabilities	2,069	3	(58 )
(Decrease) increase in deferred revenue - long term	(162 )	162	-
(Decrease) increase in other liabilities	(419 )	(138 )	1,635
Net cash (used in) provided by operating activities	(34,644)	18,387	(46,410)
Cash flows from investing activities:			
Capital expenditures	(767 )	(226 )	(2,171 )
Proceeds from sales of fixed assets	390	-	-
Proceeds from redemption of auction rate securities	100	300	1,700
Net cash (used in) provided by investing activities	(277 )	74	(471 )
Cash flows from financing activities:			
Proceeds from public offering of common stock, net of underwriting discounts and commissions and offering expenses	23,348	-	-
Proceeds from the exercise of stock options and sale of common stock under the employee stock purchase plans	306	3,726	3,896
Net cash provided by financing activities	23,654	3,726	3,896
Net (decrease) increase in cash and cash equivalents	(11,267)	22,187	(42,985)
Cash and cash equivalents at beginning of period	70,105	47,918	90,903
Cash and cash equivalents at end of period	\$58,838	\$70,105	\$47,918

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

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

1. Organization and Business

Progenics Pharmaceuticals, Inc. ("Progenics," "we" or "us") develops innovative medicines for oncology. A significant part of our research and development efforts centers on prostate specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells and also on the neovasculature of a number of other types of solid tumors. We are conducting phase 2 clinical trials of two product candidates for prostate cancer: our therapeutic candidate, PSMA ADC, a fully human monoclonal antibody-drug conjugate (ADC) directed toward PSMA, and MIP-1404, an imaging agent candidate in development by Molecular Insight Pharmaceuticals, a clinical-stage biotechnology company we acquired in January 2013 (see Note 15). Among other assets in our pipeline of targeted radiotherapy and molecular imaging compounds from the acquisition are a group of small molecule therapeutics, MIP-1095, -1555 and -1558, in preclinical study for metastatic prostate cancer and other PSMA-expressing cancers, and Azedra™, an ultra-orphan radiotherapy candidate in phase 2 study for pheochromocytoma and potential additional indications.

Progenics has developed internally and acquired from research institutions, pharmaceutical and biotechnology companies compounds and technologies which we determine to advance with other parties, including our first commercial drug, Relistor® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid induced constipation, which we have licensed to Salix Pharmaceuticals, Inc. worldwide other than Japan, where we have licensed the subcutaneous formulation of the drug to Ono Pharmaceutical Co., Ltd. In 2012, we out-licensed to MedImmune, LLC our proprietary C. difficile research program for a \$5.0 million upfront payment (received in 2013) and the right to receive potential future milestone and royalty payments, and transferred our PRO 140 HIV viral-entry inhibitor to CytoDyn Inc. for \$3.5 million cash and the right to receive potential future payments as well. We have recently suspended investment in our proprietary phosphoinositide 3-kinase (PI3K) inhibitor research and are evaluating alternative paths forward for this program. We continue to consider opportunities for strategic collaborations, out-licenses and other arrangements with biopharmaceutical companies involving our 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 upfront, commercialization milestone, royalty 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 the actions of Salix and Ono, decisions by the FDA and other regulatory bodies, such as the Complete Response Letter mentioned below, the outcome of clinical and other testing of Relistor, and, to the extent requested by our collaboration partners, our own efforts. We and Salix have sought to expand the availability of subcutaneous Relistor to patients taking opioids for non-cancer pain and who suffer from OIC as a result, and to develop an oral formulation of methylnaltrexone for use by such patients. As previously announced, the FDA in July 2012 issued a Complete Response Letter for the supplemental New Drug Application for Relistor injection for subcutaneous use for the treatment of OIC in adult patients with chronic, non-cancer pain. Salix and Progenics are continuing to work together with the FDA to generate a reasonable path forward for the further development and regulatory review of Relistor, and while is not possible to determine definitively the duration of discussions with the FDA regarding this matter, at this time Salix and Progenics anticipate a path forward could be reached with the FDA during 2013.

In 2012, we completed an underwritten public offering of 12,650 shares of common stock at a public offering price of \$2.00 per share, resulting in net proceeds of approximately \$23.3 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. None of our subsidiaries other than PSMA Development Company LLC (PSMA LLC) had operations during 2012, 2011 or 2010. 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, 2012, we held \$58.8 million in cash and cash equivalents, a decrease of \$11.3 million from \$70.1 million at December 31, 2011. We expect that this amount will be sufficient to fund operations as currently anticipated beyond one year. We may require additional funding in the future, and if we are unable to conclude favorable collaboration, license, asset sale, capital raising or other financing transactions, we will have to reduce, delay or eliminate spending on some current operations, and/or reduce salary and other overhead expenses, to extend our remaining operations. We expect to incur operating losses during the near term. At December 31, 2012, cash, cash equivalents and auction rate securities decreased \$11.3 million to \$62.1 million from \$73.4 million at December 31, 2011.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

In April 2008, our Board of Directors approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, under which we have \$12.3 million remaining available. Purchases may be discontinued at any time. We did not repurchase any common shares during 2012, 2011 and 2010. This program was terminated in March 2013.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared on the basis of accounting principles generally accepted in the U.S. (GAAP). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. 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.

Consolidation

The consolidated financial statements include the accounts of Progenics and PSMA LLC, as of and for the years ended December 31, 2012, 2011 and 2010. 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.

During 2012, 2011 and 2010, we also recognized revenue from sales of research reagents and 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 perform work under the NIH grants on a best-effort basis.

In the fourth quarter, we out-licensed our *C. difficile* program to MedImmune, LLC for a \$5.0 million upfront payment, which has been included in Accounts Receivable at December 31, 2012, and the right to receive potential future milestone and royalty payments. In consideration for the upfront payment, we are responsible for delivering relevant know-how (including patent rights) and non-reimbursable services. As of December 31, 2012, we have delivered the know-how and portion of the non-reimbursable services and as a result \$4,997 has been recognized as revenue, with the remaining \$3 related to the remaining portion of non-reimbursable services recorded in deferred revenue – current.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

Under our agreement with CytoDyn Inc. for our PRO 140 program, we received in 2012 a \$3.5 million payment and are eligible for future milestone and royalty payments. In consideration for the upfront payment, we are responsible for delivering relevant know-how (including patent rights), inventory and non-reimbursable services. Of these deliverables, which have a stand-alone value and represent separate units of accounting, we determined that the know-how and patent rights were delivered for revenue recognition purposes as of December 31, 2012, and we recognized \$2,827 as revenue from the \$3.5 million upfront payment received. As of December 31, 2012, \$673 is recorded in deferred revenue – current, which relates to the transfer of the inventory and the non-reimbursable services.

Under our license agreement, Salix is responsible for further developing and commercializing Relistor worldwide other than Japan, including completing clinical development necessary to support regulatory marketing approvals for potential new indications and formulations. We have granted Salix an exclusive license of relevant know-how, patent rights and technology, assigned relevant third-party contracts, and performed substantially all of our other transition-related activities as of June 30, 2011. During the second quarter of 2011, we and Salix completed a number of tasks involved in enabling Salix to distribute Relistor in the U.S. and Europe, as well as clinical and regulatory development related activities, and have agreed with Salix on research and development services we are to perform at Salix's direction. We have not performed any significant research and development activities during 2012 or the third and fourth quarters of 2011.

In consideration of the \$60.0 million upfront payment from Salix, we are responsible for delivering to Salix an exclusive license of relevant know-how, patent rights and technology and serving on joint committees provided for in the License Agreement. These deliverables, which have stand-alone value and represent separate units of accounting, include (i) the exclusive license which was delivered for revenue recognition purposes during the 2011 second quarter, (ii) performing reimbursable development services at Salix's direction during the 2011 second quarter, the period in which we and Salix finalized the development plan, and (iii) joint committee services, which we expect to perform through 2013. We determined that the license has stand-alone value as the license was delivered to Salix for revenue recognition purposes in the second quarter of 2011 and Salix is responsible for continuing research and development.

We developed a best estimate of selling price for each deliverable as vendor-specific objective evidence and third-party evidence was not available. We allocated the best estimate of selling price, on a relative basis, to each of the three units of accounting as the \$60.0 million upfront payment was the only payment from Salix which was fixed and determinable at the inception of the arrangement. As a result, \$58.4 million, \$1.1 million and \$0.5 million was allocated to the license, reimbursable development services and our participation in the joint committees as provided in the License Agreement, respectively. We recognized \$58.4 million for the license and relevant know-how, patent rights and technology and \$1.1 million for the reimbursable development services, respectively, during the second quarter of 2011, the period in which we delivered these items and performed the development services. We recognized \$0.2 million and \$59.6 million during 2012 and 2011, respectively. At December 31, 2012 and 2011, the remaining deferred revenue of \$0.2 million and \$0.4 million, respectively, pertaining to joint committee services, is recognized in collaboration revenue as such activities are performed in the future.

Ono is responsible for developing and commercializing subcutaneous Relistor in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono will own the filings and approvals related to subcutaneous Relistor in Japan. In addition to the \$15.0 million upfront payment from Ono, we are entitled to receive up to an additional \$20.0 million, payable upon achievement by Ono of its development milestones. Ono is also obligated to pay to us royalties and commercialization milestones on sales by Ono of subcutaneous Relistor in

Japan. Ono has the option to acquire from us the rights to develop and commercialize in Japan other formulations of Relistor, including intravenous and oral forms, on terms to be negotiated separately. Ono may request us to perform activities related to its development and commercialization responsibilities, beyond our participation in joint committees and specified technology transfer-related tasks, at its expense payable at the time we perform such services. Revenue earned from activities we perform for Ono is recorded in collaboration revenue.

We recognized the upfront payment of \$15.0 million, which we received from Ono in November 2008, as collaboration revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

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 and the likelihood of realization of deferred tax assets.

Patents

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

Net (Loss) Income Per Share

We prepare earnings per share (EPS) data in accordance with ASC 260 Earnings Per Share. Basic net (loss) income per share amounts have been computed by dividing net (loss) income by the weighted-average number of common shares outstanding during the period. For 2012 and 2010, we reported net losses and, therefore, potential common shares, amounts of unrecognized compensation expense and windfall tax benefits have been excluded from diluted net loss per share since they would be anti-dilutive. For 2011, 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. As of December 31, 2012, 2011 and 2010, our 28, 98 and 341, respectively, shares of unvested restricted stock outstanding have non-forfeitable rights to dividends. The allocation of 2012 and 2010 net losses and the 2011 net income 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 that potentially subject Progenics to concentrations of credit risk consist of cash, cash equivalents, auction rate securities and receivables from out-licensing and disposition of assets, Salix, Ono or the NIH.

We invest our excess cash in money market funds. We have established guidelines that relate to credit quality, diversification and maturity and that limit exposure to any one issue of securities. We hold no collateral for these financial instruments.

#### Cash and Cash Equivalents

We consider all highly liquid investments which have maturities of three months or less, when acquired, to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value. Cash and cash equivalents subject us to concentrations of credit risk. At December 31, 2012 and 2011, we have invested approximately \$56,224 and \$64,068, respectively, in cash equivalents in the form of money market funds with one major investment company and held approximately \$2,614 and \$6,037, respectively, in a single commercial bank.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

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 (loss) income. 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).

At December 31, 2012 and 2011, our investment in auction rate securities in the long-term assets section of the Consolidated Balance Sheets amounted to \$3,240 and \$3,332, respectively. 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 hold is 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. We re-evaluated the valuation of these securities as of December 31, 2012 and the temporary impairment amount decreased \$8 from \$268 at December 31, 2011 to \$260. All income generated from these investments was recorded as interest income (see Note 3).

Fair Value Measurements

In accordance with ASC 820 Fair Value Measurements and Disclosures, we use a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed from market data obtained from sources independent of the reporting entity (observable inputs) and the reporting entity's own assumptions about market participant assumptions developed from the best information available in the circumstances (unobservable inputs). The hierarchy level assigned to each security in our available-for-sale portfolio is based on our assessment of the transparency and reliability of the inputs used in the valuation of such instrument at the measurement date. The three hierarchy levels are defined as follows:

- 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 inputs that are unobservable and significant to the overall fair value measurement, and involve management judgment.

Other current assets are comprised of prepaid expenses, interest, deferred tax asset and other receivables of \$1,692 and \$919 at December 31, 2012 and 2011, respectively, which are expected to be settled within one year. Restricted cash

of \$150 at December 31, 2012 and \$200 at December 31, 2011, consists of collateral for a letter of credit securing lease obligations. We believe that carrying value of those assets approximates fair value.

#### Fixed Assets

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

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

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

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

## Deferred Lease Liability and Incentive

Our lease agreements include fixed escalations of minimum annual lease payments and we recognize rental expense on a straight-line basis over the lease terms and record the difference between rent expense and current rental payments as deferred rent. 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, 2012 and 2011, the Consolidated Balance Sheets include the following:

	2012	2011
Other current liabilities:		
Deferred lease incentive	\$115	\$115
Total other current liabilities	\$115	\$115
Other liabilities:		
Deferred lease liability	\$273	\$577
Deferred lease incentive	805	920
Total other liabilities	\$1,078	\$1,497

## Impairment of Long-Lived Assets

We periodically assess the recoverability of fixed assets and evaluate such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In accordance with ASC 360 Property, Plant, and Equipment – Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the carrying amount is not recoverable, we measure the amount of any impairment by comparing the carrying value of the asset to market prices for similar assets. As a result of closing our biologics pilot facilities in 2011, an impairment loss of \$22 was included in Research and development expenses in our accompanying Consolidated Statement of Operations during 2011. No impairments occurred as of December 31, 2012 or 2010.

## 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).

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  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, Wyeth 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 Ono fulfilling their manufacturing obligations, either on their own or through third-party suppliers. For 2012, 2011 and 2010, the primary sources of our revenues were Salix, Wyeth, Ono, asset out-licensing and disposition, and research grant revenues from the NIH. There can be no assurance that revenues from asset out-licensing and disposition, Salix and Ono or from research awards will continue. Substantially all of our accounts receivable at December 31, 2012 and 2011 were from the above-named sources.

Comprehensive (Loss) Income

Comprehensive (loss) income represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive (loss) income includes net (loss) income adjusted for the change in net unrealized gain or loss on auction rate securities. The disclosures required by ASC 220 Comprehensive Income for 2012, 2011 and 2010 have been included in the Consolidated Statements of Comprehensive (Loss) Income. There was no income tax expense/benefit allocated to any component of Other Comprehensive (Loss) Income (see Note 12).

Impact of Recently Adopted Accounting Standards

In June 2011, the FASB issued ASU No. 2011-05, which requires that comprehensive income and the related components be presented in a single continuous statement or in two separate but consecutive statements. The ASU was effective beginning January 1, 2012. We adopted this new standard, presenting comprehensive income in two separate but consecutive statements, and applied it retrospectively on January 1, 2012. As this guidance relates to presentation only, the adoption of this standard had no material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is the result of joint efforts by the FASB and International Accounting Standards Board to develop a single, converged fair value framework. The converged guidance specifies how to measure fair value and what disclosures to provide about fair value measurements. The ASU is effective for interim and annual periods beginning after December 15, 2011. We adopted this new standard on January 1, 2012 and it had no material impact on our consolidated financial statements.

In February 2013, The FASB issued ASU No. 2013-02, which requires presentation of amounts reclassified out of accumulated other comprehensive income by component. The ASU is effective for reporting periods beginning after December 15, 2012. We are currently evaluating the effect this ASU will have on our consolidated financial statements.

3. Fair Value Measurements

Our auction rate securities are 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 securities is recorded as a component of other comprehensive (loss) income.

The following tables present our money market funds, included in cash and cash equivalents, and auction rate securities measured at fair value on a recurring basis as of December 31, 2012 and 2011, classified by valuation hierarchy:

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

	Balance at December 31, 2012	Fair Value Measurements at December 31, 2012 Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 56,224	\$56,224	\$ -	\$ -
Auction rate securities	3,240	-	-	3,240
Total	\$ 59,464	\$56,224	\$ -	\$ 3,240

	Balance at December 31, 2011	Fair Value Measurements at December 31, 2011 Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 64,068	\$64,068	\$ -	\$ -
Auction rate securities	3,332	-	-	3,332
Total	\$ 67,400	\$64,068	\$ -	\$ 3,332

At December 31, 2012, we hold \$3,240 in auction rate securities which are classified as Level 3. The fair value of these securities includes \$2,300 of U.S. government subsidized securities collateralized by student loan obligations, with maturities greater than 10 years, and \$940 of investment company perpetual preferred stock, without a stated maturity. Auction rate securities are collateralized long-term instruments that were intended to provide liquidity through an auction process that resets interest rates at pre-determined intervals. We will not realize cash in respect of the principal amount of these securities until the issuer calls or restructures the security, the security reaches any scheduled maturity and is paid, or a buyer outside the auction process emerges. As of December 31, 2012, we have received all scheduled interest payments on these securities, which, in the event of auction failure, are reset according to the contractual terms in the governing instruments.

The valuation of auction rate securities we hold is based on Level 3 unobservable inputs which consist 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. We use a discounted cash flow model to estimate the value of these auction rate securities and the unobservable inputs consist of a redemption period ranging from four to 15 years (weighted-average: 5.9 years) and discount rates ranging from 0.125% to 2.102% (weighted-average: 0.71%). Significant increases (decreases) in the redemption period or discount rates would result in a significantly lower (higher) fair value measurement. In re-evaluating the valuation of these securities as of December 31, 2012, the temporary impairment amount, the duration of which is greater than 12 months, decreased \$8 from \$268 at December 31, 2011, to \$260, which is reflected as a part of accumulated other comprehensive loss on our accompanying Consolidated Balance Sheets and based on such re-evaluation, we believe that we have the ability to hold these securities until recovery of fair value. Due to the uncertainty related to the liquidity in the auction rate security market and therefore when individual positions may be liquidated, we have classified these auction rate securities as long-term assets on our accompanying Consolidated Balance Sheets. We continue to monitor markets for our investments and consider the impact, if any, of market conditions on the fair market value of our investments. We do not believe the carrying values of our investments are other than temporarily impaired and therefore expect the positions will eventually be liquidated without significant loss.

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS ¾ continued  
(amounts in thousands, except per share amounts or as otherwise noted)

For our financial instruments with significant Level 3 inputs (all of which are auction rate securities), the following table summarizes the activities for 2012 and 2011:

Description	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	2012	2011
Balance at beginning of period	\$3,332	\$3,608
Transfers into Level 3	-	-
Total realized/unrealized gains (losses) Included in net income (loss)	-	-
Included in comprehensive income (loss)	8	24
Settlements	(100 )	(300 )
Balance at end of period	\$3,240	\$3,332
Total amount of unrealized gains (losses) for the period included in other comprehensive loss attributable to the change in fair market value of related assets still held at the reporting date	\$-	\$-

The following tables summarize the amortized cost basis, the aggregate fair value and gross unrealized holding gains and losses at December 31, 2012 and 2011:

	Amortized Cost Basis	Fair Value	Unrealized Gain(Losses)	Holding Net
2012:				
Maturities greater than ten years:				
Auction rate securities	\$ 2,500	\$2,300	\$- \$ (200 )	\$(200)
Investments without stated maturity dates:				
Auction rate securities	1,000	940	- (60 )	(60 )
	\$ 3,500	\$3,240	\$- \$ (260 )	\$(260)
2011:				
Maturities greater than ten years:				
Auction rate securities	\$ 2,600	\$2,392	\$- \$ (208 )	\$(208)
Investments without stated maturity dates:				
Auction rate securities	1,000	940	- (60 )	(60 )
	\$ 3,600	\$3,332	\$- \$ (268 )	\$(268)

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, 2012 and 2011.  
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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

2012:	Less than 12		12 Months or		Total	
	Fair	Unrealized	Fair	Unrealized	Fair	Unrealized
Description of Securities	Value	Losses	Value	Losses	Value	Losses
Auction rate securities	\$ -	\$ -	\$3,240	\$ (260 )	\$3,240	\$ (260 )
Total	\$ -	\$ -	\$3,240	\$ (260 )	\$3,240	\$ (260 )

2011:	Less than 12		12 Months or		Total	
	Fair	Unrealized	Fair	Unrealized	Fair	Unrealized
Description of Securities	Value	Losses	Value	Losses	Value	Losses
Auction rate securities	\$ -	\$ -	\$3,332	\$ (268 )	\$3,332	\$ (268 )
Total	\$ -	\$ -	\$3,332	\$ (268 )	\$3,332	\$ (268 )

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, 2012 and 2011, there were two securities with a gross unrealized loss position of \$260 and \$268 (\$3,240 and \$3,332 of the total fair value), respectively.

The severity of the unrealized losses for auction rate securities at December 31, 2012 and 2011 ranged from 6 percent to 8 percent below amortized cost, and the weighted average duration of the unrealized losses for these securities was 58 and 46 months, respectively.

We have evaluated our individual auction rate securities holdings for other-than-temporary impairment and determined that the unrealized losses as of December 31, 2012 and 2011 are attributable to uncertainty in the liquidity of the auction rate security market. Because we do not intend to sell these securities, and believe it is not more likely than not that we would be required to sell these securities before recovery of principal, we do not consider these securities to be other-than-temporarily impaired at December 31, 2012 and 2011.

#### 4. Accounts Receivable

Our accounts receivable represent amounts due to Progenics from collaborators, royalties, research grants and the sales of research reagents. These amounts are considered to be short-term as they are expected to be collected within one year and we believe carrying value approximates fair value. Accounts receivable as of December 31, 2012 and 2011, consisted of the following:

	2012	2011
Collaborators	\$6,125	\$77
Royalties	781	1,279
Research grants	12	100
Other	19	60
Total	\$6,937	\$1,516

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

## 5. Fixed Assets

Fixed assets as of December 31, 2012 and 2011 consisted of the following:

	2012	2011
Computer equipment	\$2,166	\$2,133
Machinery and equipment	8,031	12,035
Furniture and fixtures	133	230
Leasehold improvements	5,327	11,526
Construction in progress and other	12	175
	15,669	26,099
Less, accumulated depreciation and amortization	(12,270)	(22,061)
Total	\$3,399	\$4,038

At December 31, 2012, \$2.6 million of leasehold improvements, net were being amortized over periods of 8.5-10.8 years, under leases with terms through December 31, 2020. At December 31, 2011, \$2.3 million of leasehold improvements, net were being amortized over periods of 1.3-10.8 years, 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, 2012 and 2011, consisted of the following:

	2012	2011
Accrued consulting and clinical trial costs	\$2,193	\$1,637
Accrued payroll and related costs	1,552	3,149
Restructuring accrual	813	731
Legal and professional fees	774	371
Accounts payable	229	309
Other	79	134
Total	\$5,640	\$6,331

## 7. Restructuring

We reduced headcount in the third and fourth quarters of 2011, resulting in a restructuring accrual of \$1.3 million for severance and related benefits which were paid through August 2012. We incurred other exit and contract termination costs, including expenses related to a lease amendment and consolidation of employees within reduced facility space.

We completed an additional headcount reduction in the third quarter of 2012, resulting in a restructuring accrual of \$1.9 million which is being paid through August 2013, of which we intend to pay up to \$1.2 million in shares of common stock issued pursuant to the Company's 2005 Stock Incentive Plan. During the fourth quarter of 2012, we issued \$0.1 million of common stock and at the closing market price of the Company's common stock on December

31, 2012, up to 174 shares may be issued in satisfaction of the remaining obligation.

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.

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

	Severance and Related Benefits	Other Exit Costs	Contract Termination Costs	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

## 8. Stockholders' Equity

We are authorized to issue 80.0 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 December 2012, we completed a public offering of 12,650 shares of common stock, with net proceeds of approximately \$23.3 million.

In 2008, our Board of Directors approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares. Purchases may be discontinued at any time. We did not repurchase any common shares during 2012, 2011 and 2010. At December 31, 2012, we had \$12.3 million remaining available for purchases under the program. This program was terminated in March 2013.

## 9. Commitments and Contingencies

## a. Operating Leases

As of December 31, 2012, 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. We also lease certain office equipment under non-cancelable operating leases, which expire at various times through April 2013.

As of December 31, 2012, future minimum annual payments under all operating lease agreements are as follows:

Years ending December 31,	Minimum Annual Payments
2013	\$ 2,410
2014	2,410
2015	2,470
2016	2,532
2017	2,595
Thereafter	8,182

Total \$ 20,599

Rental expense totaled approximately \$2,074, \$3,475 and \$3,544 for 2012, 2011 and 2010, respectively. For 2012 amounts paid exceeded rent expense by \$419, due to the recognition of lease incentives. For 2011 and 2010, we recognized rent expense in excess of amounts paid of \$63 and \$181, respectively, due to the recognition of escalation clauses and lease incentives. Additional facility charges, including utilities, taxes and operating expenses, for 2012, 2011 and 2010 were approximately \$2,845, \$4,033 and \$3,645, respectively.

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

## b. Licensing, Service, Supply and Related Party Agreements

Progenics has entered into intellectual property-based license and service agreements in connection with its product development programs. Progenics has recognized milestone, license and sublicense fees and supply costs, which are included in research and development expenses, totaling approximately \$1,170, \$578 and \$1,266 for 2012, 2011 and 2010, respectively.

Agreement	Paid from inception to December 31, 2012	Future (1) Commitments	Terms
Progenics agreements with:			
Lonza Sales AG	\$ 909	\$ 808	Annual license fee payments, milestones and royalties, as applicable, in respect of oncology and other products.
PSMA LLC agreements with:			
Seattle Genetics, Inc.	4,400	13,800	Milestone and periodic maintenance payments to use ADC technology to link chemotherapeutic agents to monoclonal antibodies that target prostate specific membrane antigen. ADC technology is based in part on technology licensed by SGI from third parties.
Amgen Fremont, Inc. (formerly Abgenix)	1,350	5,750	Milestones and royalties to use XenoMouse® technology for generating fully human antibodies to PSMA LLC's PSMA antigen.
Former member of PSMA LLC	241	52,216	Annual minimum royalty payments and milestones to use technology related to PSMA.

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

## 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. Two members of our Board formerly had consulting agreements; no payments in respect of these agreements have been made since 2010. We have recognized expenses with regard to the consulting agreements of \$8, \$27 and \$179 for 2012, 2011 and 2010, respectively. Those expenses include the fair value of stock options granted during 2011 and 2010, which were fully vested at grant date, of approximately \$11 and \$42, 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 MTS will receive a monthly retainer of \$10 during the term of the agreement (which may be terminated by either party on 30 days notice), \$300 for MTS' services in connection with the Molecular Insight acquisition described in Note 15, and in connection with other transactions, if any, as to which MTS provides services to the Company, such other amounts as the parties may mutually agree.

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PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

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. During the second quarter of 2011, we accelerated the vesting of outstanding awards to non-management employees in connection with a change in program eligibility and termination of the Company's employee stock purchase plans. 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.

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 8,450 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 usually vests 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, 2012, 2011 and 2010, all outstanding stock options were non-qualified options. The 2005 Plan will terminate in April 2015; 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 2012, 2011 and 2010 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 (excluding our former CEO in 2011 and 2010), we are using expected terms of 5.4 and 7.4 years, 5.3 and 7.4 years, and 5.3 and 7.3 years, respectively. The expected term of stock options granted to our former CEO in 2011 and 2010 was calculated separately from stock options granted to employees and directors and officers, and was 8 years for 2011 and 2010. 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 2012, 2011 and 2010:

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS <sup>3</sup>/<sub>4</sub> continued  
(amounts in thousands, except per share amounts or as otherwise noted)

	2012	2011	2010
Expected volatility	70% – 85%	68% – 78%	68% – 87%
Expected dividends	Zero	zero	zero
Expected term (years)	5.3 – 10	5.3 – 10	5.3 – 10
Weighted average expected term (years)	6.11	6.17	6.92
Risk-free rate	0.57% – 1.71%	0.77% – 2.97%	1.21% – 3.09%

A summary of option activity under the Plans as of December 31, 2012 and changes during the year then ended is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Yr.)	Aggregate Intrinsic Value
Outstanding at January 1, 2012	5,597	\$ 12.60		
Granted	814	9.54		
Exercised	(38 )	5.28		
Forfeited or expired	(1,007)	12.16		
Outstanding at December 31, 2012	5,366	\$ 12.27	5.61	\$ 1
Exercisable at December 31, 2012	3,970	\$ 13.72	4.77	\$ 1

The weighted average grant-date fair value of options granted under the Plans during 2012, 2011 and 2010 was \$6.38, \$5.51 and \$3.10, respectively. The total intrinsic value of options exercised during 2012, 2011 and 2010 was \$174, \$345 and \$0, respectively.

The options granted under the Plans, described above, include 33, 113, 38, 75, 145 and 113 non-qualified stock options granted to our former CEO on July 1, 2002, 2003, 2004 and 2005, on July 3, 2006 and on July 2, 2007, respectively, which cliff vest after nine years and 11 months from the respective grant date. All but the 2006 awards are fully vested. Vesting of a defined portion of each award will occur earlier if a defined performance condition is achieved; more than one condition may be achieved in any period. In accordance with ASC 718 Compensation – Stock Compensation, at the end of each reporting period, we will estimate the probability of achievement of each performance condition and will use those probabilities to determine the requisite service period of each award. 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. The implied service periods related to the performance conditions were the estimated times for each performance condition to be achieved. Thus, compensation expense was recognized over the shortest estimated time for the achievement of performance conditions for that award (assuming that the performance conditions were to be achieved before the cliff vesting occurred). On July 1, 2008, 2009 and 2010, we granted awards to our former CEO (consisting of options in 2010 and 2009 and options and restricted stock in 2008) and on July 1, 2010 to our CEO (consisting of options) which vest on the basis of the achievement of specified performance or market-based milestones. In connection with our former CEO's retirement in 2012 the 2004, 2007, 2008, 2009 and 2010 performance or market-based awards have been fully vested as a result of accelerated vesting during 2012. The options have an exercise price equal to the closing price of our

common stock on the date of grant. The awards are valued using a Monte Carlo simulation model. On July 1, 2011 and March 1, 2012, we granted option awards to our CEO which vests on the basis of the achievement of specified performance-based milestones. The options have exercise prices equal to the closing price of our common stock on the dates of grant. The awards are valued using the Black-Scholes option pricing model. The expense related to the grants with performance and market-based milestones will be recognized over the shortest estimated time for the achievement of the performance or market conditions. The awards will not vest unless one of the milestones is achieved or the market condition is met. Changes in the estimate of probability of achievement of any performance or market condition will be reflected in compensation expense of the period of change and future periods affected by the change.

At December 31, 2012, the estimated requisite service periods for the 2006, 2010, 2011 and 2012 awards, described above, were 3.5, 1.0, 2.0 and 2.0 years, respectively. For 2012, 2011 and 2010, the total compensation expense recognized for the performance-based options was \$2.0 million, \$0.4 million and \$1.1 million, respectively.

A summary of the status of our outstanding restricted stock awarded under the Plans which has not yet vested as of December 31, 2012 and changes during the year then ended is presented below:

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

Restricted Stock Awards	Shares	Weighted Average Grant-Date Fair Value
Nonvested at January 1, 2012	98	\$ 7.40
Granted	-	-
Vested	(64 )	8.50
Forfeited	(6 )	5.35
Nonvested at December 31, 2012	28	\$ 5.35

Two employee stock purchase plans (the Purchase Plans), the 1998 Employee Stock Purchase Plan (the Qualified Plan) and the 1998 Non-Qualified Employee Purchase Plan (the Non-Qualified Plan), as amended, provided for the issuance of up to 4,400 and 1,100 shares of common stock, respectively. Issuances of common stock under the Purchase Plans, terminated by the Company during the second quarter of 2011, provided for the grant to all employees of options to use an amount equal to 25% of their quarterly compensation, as such percentage was determined by the Board of Directors prior to the date of grant, to purchase shares of our common stock at a price per share equal to the lesser of the fair market value of the common stock on the date of grant or 85% of the fair market value on the date of exercise. Options were granted automatically on the first day of each fiscal quarter and expired six months after the date of grant. The Qualified Plan was not available to employees owning more than five percent of the common stock and imposed certain other quarterly limitations on option grants. Options under the Non-Qualified Plan were granted to the extent that option grants were restricted under the Qualified Plan.

The fair value of shares purchased under the Purchase Plans was estimated on the date of grant in accordance with ASC 718 Compensation – Stock Compensation, via the same option valuation model used for options granted under the Plans, but with the following assumptions during 2011 and 2010:

	2011	2010
Expected volatility	43% – 51%	45% – 72%
Expected dividends	zero	zero
Expected term	6 months	6 months
Risk-free rate	0.06% – 0.22%	0.11% – 0.18%

Purchases of common stock under the Purchase Plans during 2011 and 2010 are summarized as follows:

	Qualified Plan			Non-Qualified Plan		
	Shares	Weighted Average Grant-Date Fair Value		Shares	Weighted Average Grant-Date Fair Value	
	Purchase Price Range			Purchase Price Range		
2011	428	\$4.62 – \$5.65	\$ 0.88	162	\$4.62 – \$5.65	\$ 0.84
2010	802	\$3.50 – \$4.56	\$ 0.94	208	\$3.75 – \$4.56	\$ 0.96

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 2012, 2011 and 2010 was:

	2012	2011	2010
Recognized as:			
Research and Development	\$4,568	\$4,499	\$5,091
General and Administrative	1,968	1,863	4,424
Total	\$6,536	\$6,362	\$9,515

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, 2012, there was \$5.1 million and \$0.1 million of total unrecognized compensation cost related to non-vested stock options under the 1996 and 2005 Plans and non-vested restricted shares, respectively. Those costs are expected to be recognized over weighted average periods of 1.8 years and 0.5 years, respectively. Cash received from exercises under all share-based payment arrangements for 2012 was \$0.3 million. We issue new shares of our common stock upon share option exercise and share purchase.

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 incurred net losses for 2012 and 2010 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 2012 and 2010 periods. We reported net income for 2011 and included the dilutive effect of unrecognized compensation expense in the assumed proceeds in the denominator of the diluted EPS calculation. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls, for purposes of diluted EPS calculation, excluding the impact of deferred tax assets. This policy decision will apply when we have net income and windfall tax benefits/shortfalls are realizable.

#### 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, 2012, 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 \$535, \$597 and \$594 to the Amended Plan for 2012, 2011 and 2010, 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.

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS <sup>3</sup>/<sub>4</sub> continued

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

There is no provision or benefit for federal or state income taxes for 2012, 2011 or 2010 other than a federal tax refund of \$95 we received in 2010 from new legislation permitting the carryback of net operating losses (NOLs) to 2005 as well as permitting the suspension of limitations on alternative minimum tax NOL utilization. We have completed a calculation through March 31, 2011, under Internal Revenue Code Section 382, the results of which indicate that past ownership changes will limit utilization of NOLs in the future. Ownership changes subsequent to March 31, 2011, 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, 2012 and 2011, consisted of the following:

	2012	2011
Deferred tax assets:		
Depreciation and amortization	\$6,497	\$6,865
R&E tax credit carry-forwards	11,843	11,966
NYS investment tax credit carry-forwards	1,084	1,088
AMT credit carry-forwards	211	211
Net operating loss carry-forwards	112,966	85,110
Capitalized research and development expenditures	30,884	43,113
Stock compensation	14,436	13,789
Other items	2,193	3,600
Total gross deferred tax assets	180,114	165,742
Less: Valuation allowance	(178,045)	(165,742)
Deferred tax assets	2,069	-
Deferred tax liability - current	(2,069)	-
Net deferred tax asset (liability)	\$-	\$-

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 2012, we incurred net losses for tax purposes. For 2011, we had income for tax purposes and such amount was offset completely by our available net operating loss carry-forwards. We recognized a full tax valuation against deferred taxes at December 31, 2012 and 2011. In 2012, we recognized deferred income tax assets, net of a valuation allowance, of \$2,069 (\$17 in current assets and \$2,052 in non-current assets) and deferred income tax liabilities of \$2,069 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. The recognition of these deferred income tax assets and liabilities had no effect on our net loss for 2012.

The following is a reconciliation of income taxes computed at the Federal statutory income tax rate to the actual effective income tax provision during 2012, 2011 and 2010:

	2012	2011	2010
U.S. Federal statutory rate	(35.0)%	35.0%	(34.0)%
State income taxes, net of Federal benefit	(5.4)	8.0	(5.1)
Research and experimental tax credit	-	(4.1)	(1.7)
Change in valuation allowance	34.7	(22.6)	38.2
Effect of federal tax rate bracket change on valuation allowance	-	(34.8)	-

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Equity compensation	4.2	17.0	2.3
Investment tax credit	-	(0.1)	0.1
Other	1.5	1.6	0.1
Income tax provision (benefit)	0.0%	0.0%	(0.1)%

As of December 31, 2012, we had available, for tax return purposes, unused NOLs of approximately \$298.0 million, which will expire in various years from 2021 to 2032, \$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, \$11.4 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.

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. During 2012, 2011 and 2010, we had no unrecognized tax benefits resulting from tax positions during a prior or current period, settlements with taxing authorities or the expiration of the applicable statute of limitations. 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. 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.

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

As of December 31, 2012, 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 1995, with the exception of 1997 and 2011, during which we reported net income. No amounts of interest or penalties were recognized in our Consolidated Statements of Operations or Consolidated Balance Sheets as of and for 2012, 2011 and 2010.

Our research and experimental (R&E) tax credit carry-forwards of approximately \$11.8 million at December 31, 2012 expire in various years from 2018 to 2032. During 2012, research and experimental tax credit carry-forwards of approximately \$125 expired. The American Taxpayer Relief Act of 2012, enacted on January 2, 2013, retroactively reinstated the federal research and development credit for 2012 and extended these credits through 2013.

## 13. Net Income (Loss) Per Share

Our basic net (loss) income per share amounts have been computed by dividing net (loss) income by the weighted-average number of common shares outstanding during the period. For 2012 and 2010, we reported net losses and, therefore, potential common shares were not included since such inclusion would have been anti-dilutive. For 2011, 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. As of December 31, 2012, 2011 and 2010, our 28, 98 and 341, respectively, shares of unvested restricted stock outstanding have non-forfeitable rights to dividends. The allocation of 2012 and 2010 net losses and the 2011 net income 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:

	Net (Loss) Income (Numerator)	Weighted Average Common Shares (Denominator)	Per Share Amount
2012:			
Basic and diluted	\$ (35,431 )	34,754	\$ (1.02 )
2011:			
Basic	\$ 10,381	33,375	\$ 0.31
Dilutive effect of stock options	-	66	
Dilutive effect of restricted stock	-	53	
Diluted	\$ 10,381	33,494	\$ 0.31
2010:			
Basic and diluted	\$ (69,725 )	32,590	\$ (2.14 )

During 2012, 2011 and 2010, anti-dilutive common shares excluded from diluted per share amounts consist of the following:

2012	2011	2010
Weighted	Weighted	Weighted
Average	Average	Average
Number	Number	Number
Exercise	Exercise	Exercise

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	Price		Price		Price	
Options	5,947	\$ 12.32	4,543	\$ 14.92	5,037	\$ 15.17
Restricted stock	60		45		45	
Total	6,007		4,588		5,082	

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## PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  $\frac{3}{4}$  continued  
(amounts in thousands, except per share amounts or as otherwise noted)

## 14. Unaudited Quarterly Results (unaudited)

Summarized quarterly financial data during 2012 and 2011 are as follows:

	2012 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues <sup>(1)</sup>	\$2,226	\$1,820	\$1,117	\$8,885
Net loss	(13,086)	(10,720)	(11,301)	(324)
Net loss per share - basic and diluted	(0.39)	(0.32)	(0.33)	(0.01)
	2011 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues <sup>(2)</sup>	\$2,388	\$74,407	\$5,804	\$2,197
Net income (loss)	(22,927)	55,486	(11,432)	(10,746)
Net income (loss) per share - basic	(0.69)	1.66	(0.34)	(0.32)
Net income (loss) per share - diluted	(0.69)	1.64	(0.34)	(0.32)

<sup>(1)</sup> Revenues in the fourth quarter of 2012 include \$5.0 million and \$2.8 million from the MedImmune and CytoDyn Agreements, respectively.

<sup>(2)</sup> Revenues in the second quarter of 2011 include \$59.5 million from the Salix Agreement

## 15. Subsequent Event

We acquired MIP in January 2013 pursuant to a Stock Purchase and Sale Agreement with its stockholders and their representative, under which we purchased all of MIP's outstanding capital stock in consideration of the issuance by Progenics to the stockholders of 4,566 shares (500 of which is in escrow) of Progenics common stock in a private transaction exempt from the registration requirements of the U.S. Securities Act of 1933 and therefore subject to transfer restrictions at the time of issuance. (The closing NASDAQ market price of Progenics' freely transferable common shares on January 18, 2013, the date this acquisition was consummated, was \$2.83 per share.) Under the Agreement, Progenics also agreed to pay to the stockholders potential milestones, in cash or Progenics stock at Progenics' 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 all MIP products. The Agreement contains customary representations and warranties regarding MIP, the stockholders, their representative, and Progenics, as well as covenants, indemnification and other provisions. This acquisition is to be accounted for using the acquisition method of accounting. As of the completion of the acquisition, MIP's assets and liabilities will be recorded at their respective fair values and added to those of Progenics. The final determination of acquisition consideration results from the completion of the analysis of the fair value of MIP's assets and liabilities and any difference between the acquisition consideration and the fair value of the identifiable net assets is to be recorded as goodwill.

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## SIGNATURES

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

PROGENICS PHARMACEUTICALS,  
INC.

By: /s/ MARK R. BAKER

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

Date: March 14, 2013

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

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
/s/ PETER J. CROWLEY Peter J. Crowley	Chairman	March 14, 2013
/s/ PAUL J. MADDON Paul J. Maddon, M.D., Ph.D.	Vice Chairman	March 14, 2013
/s/ MARK R. BAKER Mark R. Baker	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2013
/s/ CHARLES A. BAKER Charles A. Baker	Director	March 14, 2013
/s/ KURT W. BRINER Kurt W. Briner	Director	March 14, 2013
/s/ STEPHEN P. GOFF Stephen P. Goff, Ph.D.	Director	March 14, 2013
/s/ DAVID A. SCHEINBERG David A. Scheinberg, M.D., Ph.D.	Director	March 14, 2013
/s/ NICOLE S. WILLIAMS Nicole S. Williams	Director	March 14, 2013
/s/ ANGELO W. LOVALLO, JR. Angelo W. Lovallo, Jr.	Senior Executive Director, Financial Reporting and Treasurer (Principal Financial and Accounting Officer)	March 14, 2013

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## EXHIBIT INDEX

Exhibit Number *	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(2)	Amended and Restated By-laws of the Registrant.
4.1(3)	Specimen Certificate for Common Stock, \$0.0013 par value per share, of the Registrant.
10.1(3)	Form of Registration Rights Agreement.
10.2(3)	1989 Non-Qualified Stock Option Plan‡
10.3(3)	1993 Stock Option Plan, as amended‡
10.4(3)	1993 Executive Stock Option Plan‡
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(8)	Employment Agreement, dated December 31, 2007, between the Registrant and Dr. Paul J. Maddon‡
10.8.1(9)	First Amendment to Employment Agreement, dated March 31, 2011, between the Registrant and Dr. Paul J. Maddon‡
10.8.2(10)	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(11)†	Development and License Agreement, dated April 30, 1999, between Protein Design Labs, Inc. and the Registrant.
10.16.1(12)	Letter Agreement, dated November 24, 2003, relating to the Development and License Agreement between Protein Design Labs, Inc. and the Registrant.
10.18(13)	Director Stock Option Plan‡
10.19(14)†	Exclusive Sublicense Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.19.1(15)	Amendment to Exclusive Sublicense Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.21.1(16)	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 2012 Annual Meeting of Stockholders and is incorporated herein by reference.‡
10.25(17) †	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., (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., and (iii) Letter Agreement Related to Progenics' Relistor In-License dated, December 22, 2005, by and among the University of Chicago, acting on behalf of itself and ARCH Development Corporation, the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Wyeth, acting through its Wyeth Pharmaceuticals Division.
10.26(18)	Membership Interest Purchase Agreement, dated April 20, 2006, between the Registrant Inc. and Cytogen Corporation.
10.27(18) †	Amended and Restated PSMA/PSMP License Agreement, dated April 20, 2006, by and among the Registrant, Cytogen Corporation and PSMA Development Company LLC.
10.28(19)	Consulting Agreement, dated May 1, 1995, between Active Biotherapies, Inc. and Dr. David A. Scheinberg, M.D., Ph.D., as amended on June 13, 1995, as assigned to the Registrant, and as amended on

January 1, 2001‡

10.29(20) † License Agreement, dated as of October 16, 2008, by and among Ono Pharmaceutical Co., Ltd. and the Registrant.

10.30(20) † Partial Termination and License Agreement, dated October 16, 2008, by and among Wyeth, acting through Wyeth Pharmaceuticals Division, Wyeth-Whitehall Pharmaceuticals, Inc. and Wyeth-Ayerst Lederle, Inc. and the Registrant and Progenics Pharmaceuticals Nevada, Inc.

10.31(20) † Consent, Acknowledgment and Agreement, dated as of October 16, 2008, by and among Wyeth, acting through Wyeth Pharmaceuticals Division, Wyeth-Whitehall Pharmaceuticals, Inc. and Wyeth-Ayerst Lederle, Inc., the Registrant and Ono Pharmaceutical Co., Ltd.

10.32(20) † 2008 Agreement Related to Progenics' MNTX In-License, dated October 16, 2008, by and among the University of Chicago, acting on behalf of itself and ARCH Development Corporation, the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Ono Pharmaceutical Co., Ltd.

10.33(21) † Termination and Transition Agreement, effective as of October 1, 2009, by and among Wyeth, acting through Wyeth Pharmaceuticals Division, Wyeth-Whitehall Pharmaceuticals, Inc., Wyeth-Ayerst Lederle, Inc., and AHP Manufacturing B.V., and the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Excelsior Life Sciences Ireland Limited.

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10.33.1(22) †	First Amendment to Termination and Transition Agreement, effective as of October 1, 2010, by and among Wyeth LLC, acting through Wyeth Pharmaceuticals Division, Wyeth-Whitehall Pharmaceuticals LLC, Wyeth-Ayerst Lederle LLC, and AHP Manufacturing B.V., and the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Excelsior Life Sciences Ireland Limited.
10.34(23) †	Collaboration Agreement, effective June 14, 2005, by and between Seattle Genetics, Inc. and PSMA Development Company, LLC.
10.37(9) †	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(9) †	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.
12.1	Statement re computation of ratio of earnings (loss) to combined fixed charges and preferred stock dividends.
21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP.
23.2	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., Senior Executive Director, Financial Reporting & 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., Senior Executive Director, Financial Reporting & 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
101.DEF	XBRL Taxonomy Extension Definition Document

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

- (1) Previously filed in Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.
- (2) Previously filed in Current Report on Form 8-K filed on March 16, 2012.
- (3) Previously filed in Registration Statement on Form S-1, Commission File No. 333-13627.
- (4) Previously filed in Registration Statement on Form S-8, Commission File No. 333-120508.
- (5) Previously filed in Current Report on Form 8-K filed on November 28, 2012.
- (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 quarterly period ending March 31, 2007
- (8) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2007.
- (9) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.
- (10) Previously filed in Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

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- (11) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1999.
- (12) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2004.
- (13) Previously filed in Annual Report on Form 10-K for the year ended December 31, 1999.
- (14) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2002.
- (15) Previously filed in Current Report on Form 8-K filed on September 20, 2004.
- (16) Previously filed in Current Report on Form 8-K filed on November 28, 2012.
- (17) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2005.
- (18) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ending June 30, 2006.
- (19) Previously filed in Annual Report on Form 10-K/A for the year ended December 31, 2006.
- (20) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2008.
- (21) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2009.
- (22) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2010.
- (23) Previously filed in Amendment No. 2 to Annual Report on Form 10-K/A for the year ended December 31, 2009.

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

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