



2008 Annual Report



This annual report contains 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; 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, such as those relating to the recently-announced acquisition of our RELISTOR® collaborator, Wyeth Pharmaceuticals, by Pfizer Inc.; potential product liability; intellectual property, litigation, environmental and other risks; the risk that licenses to 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 reports filed with the U.S. Securities and Exchange Commission. In particular, we cannot assure you that RELISTOR will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, or that any of our other programs will result in a commercial product.

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any statements as a result of new information or future events or developments. It should not be assumed that our silence over time means that actual events are bearing out as expressed or implied in forward-looking statements.

# A Message from the CEO

Dear Shareholders, Employees and Friends,

**In 2008, Progenics Pharmaceuticals achieved its first U.S. product approval: RELISTOR®. This first-in-class drug is now approved in over 30 countries.**

Progenics has entered a new era since our first commercial product approval. Following FDA approval last April, our collaborator, Wyeth Pharmaceuticals, began full commercialization of subcutaneous RELISTOR in August for the treatment of advanced-illness patients with opioid-induced constipation (OIC) – an area of critical unmet medical need in an important population. Since the launch, we have been working to extend the benefits of this novel drug to broader populations and other markets. Part of this effort has been demonstrated by the successful completion of a pivotal phase 3 trial in chronic pain patients. In October, we signed a license agreement with Ono Pharmaceutical Co., Ltd. for the development and commercialization of subcutaneous RELISTOR in Japan.

## **ONCOLOGY: PSMA ADC for the treatment of prostate cancer**

We also made significant progress in our clinical programs, initiating clinical trials of our investigational drug, PSMA ADC, for the treatment of metastatic prostate cancer. PSMA ADC is a monoclonal antibody-drug conjugate that targets prostate-specific membrane antigen, a protein abundantly expressed on prostate cancer cells, making it a promising therapeutic target. PSMA ADC is comprised of our fully human monoclonal antibody to PSMA that is linked (conjugated) to a potent chemotherapeutic drug. PSMA ADC is designed to release the chemotherapeutic payload after entering the targeted cancer cell, substantially reducing exposure of surrounding non-cancerous cells to the toxic effects of systemic chemotherapy. We expect to report initial results from these clinical studies in the second half of 2009.

We also initiated a clinical trial of a novel PSMA-targeted therapeutic vaccine designed to prevent the relapse and recurrence of prostate cancer.

## **VIROLOGY: PRO 140 for the treatment of HIV/AIDS**

Our HIV program also had meaningful advances in 2008. PRO 140, our FDA-designated Fast Track investigational humanized monoclonal antibody for the treatment of HIV/AIDS, successfully completed two, phase 2 clinical trials in which both subcutaneous and intravenous formulations exhibited robust, potent and prolonged activity in HIV-infected individuals. We are developing PRO 140 as an injection to be self-administered, once weekly. We plan to meet with FDA this year to determine the next steps in the development of this novel viral-entry inhibitor.

While advancing our clinical programs, we are also guided by a conservative financial strategy, especially during these challenging economic times. Our significant progress during 2008 was made possible by the financial support of our collaborators, Wyeth and Ono, in the form of upfront and milestone payments, reimbursement by Wyeth of development expenses, and royalties on worldwide sales of RELISTOR. In addition, Progenics has been awarded approximately \$70 million in U.S. government grants to date.

We are proud of our strong financial position. Going forward, we will continue to seek multiple non-dilutive revenue sources to conduct leading-edge research and development on our own and through existing and new industry relationships. We will also continue to set an example of leadership and innovation in the biotechnology industry while generating value for our shareholders.

I thank you for your continued support.

Sincerely,



Paul J. Maddon, M.D., Ph.D.  
Founder, Chief Executive Officer and Chief Science Officer  
April 27, 2009

# Corporate Information

## Senior Management

Paul J. Maddon, M.D., Ph.D.  
Founder, Chief Executive Officer and  
Chief Science Officer

Mark R. Baker, J.D.  
Executive Vice President - Corporate

Robert A. McKinney, CPA  
Senior Vice President, Finance and  
Operations & Chief Financial Officer  
and Treasurer

Thomas A. Boyd, Ph.D.  
Senior Vice President, Product  
Development

Robert J. Israel, M.D.  
Senior Vice President, Medical Affairs

William C. Olson, Ph.D.  
Senior Vice President, Research and  
Development

Benedict Osorio, M.S., M.B.A.  
Senior Vice President, Quality

Nitya G. Ray, Ph.D.  
Senior Vice President, Manufacturing

Ann Marie Assumma, M.S.  
Vice President, Regulatory Affairs

Walter M. Capone, M.B.A.  
Vice President, Commercial  
Development and Operations

Richard W. Krawiec, Ph.D.  
Vice President, Corporate Affairs

Tage Ramakrishna, M.D.  
Vice President, Clinical Research

## Board of Directors

Kurt W. Briner  
Chairman of the Board  
President and Chief Executive  
Officer (Retired)  
Sanofi Pharma S.A.

Charles A. Baker  
Chairman, President and Chief  
Executive Officer (Retired)  
The Liposome Company, Inc.

Peter J. Crowley  
Head of Healthcare Investment Banking,  
CIBC World Markets (Retired)

Mark F. Dalton  
President  
Tudor Investment Corporation

Stephen P. Goff, Ph.D.  
Higgins Professor  
Biochemistry and Microbiology  
Columbia University  
Investigator, Howard Hughes  
Medical Institute

Paul J. Maddon, M.D., Ph.D.  
Founder, Chief Executive Officer  
and Chief Science Officer  
Progenics Pharmaceuticals, Inc.

David A. Scheinberg, M.D., Ph.D.  
Vincent Astor Chair and Chairman,  
Molecular Pharmacology and  
Chemistry Program  
Sloan-Kettering Institute;  
Professor of Medicine and Pharmacology,  
Weill/Cornell Medical College

Nicole S. Williams  
Executive Vice President and Chief  
Financial Officer (Retired)  
Abraxis Bioscience, Inc.  
and President (Retired) of Abraxis  
Pharmaceutical Products (a division  
of Abraxis Bioscience, Inc.)

**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, 2008**
- Or**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

Commission File No. 000-23143

**PROGENICS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**13-3379479**  
(I.R.S. Employer Identification Number)

**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**  
**Common Stock, par value \$0.0013 per share**

**Name of each exchange on which registered**  
**The NASDAQ Stock Market LLC**

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

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

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

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

Indicate by check mark 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, 2008, based upon the closing price of the Common Stock on The NASDAQ Stock Market LLC on that date of \$15.87 per share, was \$244,987,904 (1).

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

As of March 6, 2009, 30,782,252 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 2009 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 contains 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; 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, such as those relating to the recently-announced acquisition of our RELISTOR<sup>®</sup> collaborator, Wyeth Pharmaceuticals, by Pfizer, Inc.; potential product liability; intellectual property, litigation, environmental and other risks; the risk that licenses to intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.*

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

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any statements as a result of new information or future events or developments. Thus, 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>.

## Item 1. Business

Progenics Pharmaceuticals, Inc. is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward supportive care, virology and oncology. We commenced principal operations in 1988, became publicly traded in 1997 and throughout have been engaged primarily in research and development efforts, developing manufacturing capabilities, establishing corporate collaborations and raising capital.

In the area of **supportive care**, our first commercial product, **RELISTOR® (methylnaltrexone bromide)**, was approved by the U.S. Food and Drug Administration (FDA) for sale in the United States in April 2008. Our collaboration partner, Wyeth Pharmaceuticals, commenced sales of RELISTOR subcutaneous injection in June, and we have begun earning royalties on world-wide sales. Regulatory approvals have also been obtained in Canada, the European Union, Australia and Venezuela, and marketing applications have been approved or are pending or scheduled in other countries. In October, we out-licensed to Ono Pharmaceutical Co., Ltd., Osaka, Japan, the rights to subcutaneous RELISTOR in Japan. We continue development and clinical trials with respect to other indications for RELISTOR and our other product candidates.

In January 2009, Wyeth and Pfizer Inc. announced a definitive agreement under which Pfizer is to acquire Wyeth. We understand that the transaction is currently expected to close in late 2009 and is subject to a variety of conditions. The proposed acquisition of Wyeth by Pfizer does not trigger any change-of-control provisions in our collaboration with Wyeth, and we believe that if the acquisition occurs, the combined Pfizer/Wyeth organization will continue to have the same rights and responsibilities under the collaboration following the acquisition as Wyeth had before. We cannot, however, predict how a combined Pfizer and Wyeth may view the utility and attractiveness of our collaboration. See *Supportive Care, Licenses – Progenics' Licenses – Wyeth and Risk Factors -- We are dependent on Wyeth and Ono to develop and commercialize RELISTOR in their respective areas, exposing us to significant risks, including that Wyeth's announced acquisition by Pfizer may adversely affect our Collaboration*, below.

In the area of **virology**, we are developing two viral-entry inhibitors: a humanized monoclonal antibody, **PRO 140**, for treatment of human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), and a proprietary orally-available small-molecule drug candidate, designated **PRO 206**, for treatment of hepatitis C virus infection (HCV). We have recently selected for further clinical development the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for convenient, weekly self-administration, and we are conducting preclinical development activities in preparation for filing an Investigational New Drug (IND) application for PRO 206. We are also engaged in research regarding a prophylactic vaccine against HIV infection. See *Virology*, below.

In the area of **prostate cancer**, we are conducting a phase 1 clinical trial of a fully human monoclonal antibody-drug conjugate (ADC) directed against 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 also developing therapeutic vaccines designed to stimulate an immune response to PSMA. See *Oncology – Prostate Cancer*, below.

**Product Licensing.** We also seek out promising new products and technologies around which to build new development programs or enhance existing programs. We own the worldwide commercialization rights to each of our product candidates except RELISTOR, commercialization of which is the responsibility of Wyeth and Ono in their respective territories. We may also seek collaboration partners to accelerate development and assist in achieving full commercialization of our product candidates.

Following is a summary of our principal programs and product candidates:

<b>Lead commercial product</b>	<b>Approved indication</b>	<b>Status</b>
<b>Supportive Care</b>		
RELISTOR-Subcutaneous injection	Approved U.S. label: Treatment of opioid-induced constipation (OIC) in advanced illness patients receiving palliative care when laxative therapy has not been sufficient (note 1).	Marketed in the U.S., E.U., Australia, Canada, Venezuela and elsewhere.
<b>Program/product candidates</b>	<b>Proposed therapeutic area</b>	<b>Status (note 2)</b>
<b>Supportive Care</b>		
RELISTOR-Subcutaneous injection	Treatment of OIC in patients with chronic pain not related to cancer.	Phase 3
RELISTOR-Subcutaneous injection	Treatment of OIC in patients during rehabilitation from an orthopedic surgical procedure.	Phase 2
RELISTOR-Intravenous	Management of post-operative ileus.	Phase 3
RELISTOR-Oral	Treatment of OIC.	Phase 2
<b>Virology</b>		
<b>Human Immunodeficiency Virus (HIV)</b>		
PRO 140	Treatment of HIV infection.	Phase 2
ProVax	Treatment and prevention of HIV infection.	Research
<b>Hepatitis C Virus (HCV)</b>		
PRO 206	Treatment of HCV infection.	Preclinical
<b>Oncology</b>		
<b>Prostate cancer/ PSMA-based therapies</b>		
PSMA ADC	Treatment of prostate cancer.	Phase 1
Recombinant protein vaccine (rsPSMA)	Immunotherapy for prostate cancer.	Phase 1
Viral-vector vaccine (PSMA VRP)	Immunotherapy for prostate cancer.	Phase 1

(1) RELISTOR is a Wyeth trademark. The 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).

(2) Research means initial research related to specific molecular targets, synthesis of new chemical entities, assay development or screening for identification of lead compounds.

Pre-clinical means a lead compound undergoing toxicology, formulation and other testing in preparation for clinical trials.

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

Phase 1: Initial evaluation of safety in humans; study method of action and metabolism.

Phase 2: Evaluation of safety, dosing and activity or efficacy; continue safety evaluation.

Phase 3: Larger scale evaluation of safety, efficacy and dosage.

## Supportive Care

**About Opioids.** Opioid-based medications such as morphine and codeine are the mainstay of health care practitioners to control moderate-to-severe pain. We estimate that in 2007 approximately 240 million prescriptions for opioids were written in the U.S. Physicians prescribe opioids for patients receiving palliative care, undergoing surgery or experiencing chronic pain, as well as for other medical conditions.

Opioids relieve pain by interacting with receptors located in the brain and spinal cord, which comprise the central nervous system. At the same time, opioids also activate receptors outside the central nervous system, often resulting in constipation. As a result of opioid-induced constipation (OIC), many patients may stop or reduce their opioid therapy, opting to endure pain in order to obtain relief from their OIC and its associated side effects.

**RELISTOR**, the first approved treatment for OIC that addresses the underlying mechanism of OIC, is a selective, peripherally acting, mu-opioid-receptor antagonist that decreases the constipating side effects induced by opioid pain medications in the gastrointestinal tract without diminishing the ability of these medications to relieve pain. Relief of OIC is an important need not adequately met by any other approved drug. Because of its chemical composition, RELISTOR has restricted ability to cross the blood-brain barrier and enter the central nervous system, where pain is perceived. Outside the central nervous system, RELISTOR competes with opioid pain medications for binding sites on opioid receptors, displacing the pain medications only in the periphery and selectively “turning off” the constipating effects of those medications on the gastrointestinal tract without affecting pain relief occurring in the central nervous system.

**Subcutaneous RELISTOR.** In 2008, we earned \$25.0 million in milestone payments from Wyeth for FDA and European approvals of subcutaneous RELISTOR for the advanced illness setting, and in the second quarter of 2008 we began earning royalties on Wyeth’s sales of that product. RELISTOR net sales and related royalties earned in 2008 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* and our financial statements elsewhere in this document.

Quarter Ended	Net Sales By Wyeth	Royalties Earned
	(in thousands)	
June 30, 2008	\$ 2,100	\$ 321
September 30, 2008	800	117
December 31, 2008	1,500	227
Total	<u>\$ 4,400</u>	<u>\$ 665</u>

We and Wyeth are also developing subcutaneous RELISTOR for treatment of OIC outside the advanced illness setting, in individuals with chronic pain not related to cancer, such as severe back pain that requires treatment with opioids (a phase 3 trial conducted by Wyeth), and in individuals rehabilitating from an orthopedic surgical procedure in whom opioids are used to control post-operative pain (a hypothesis-generating phase 2 trial conducted by us). We are no longer enrolling patients in this latter trial and are analyzing data from the treated population. Based on positive results from the one-month blinded portion of the phase 3 chronic pain study, we and Wyeth recently initiated an FDA-required one-year, open-label safety study in chronic, non-cancer pain patients which is intended to yield a consolidated safety database to enable filing a supplemental New Drug Application (sNDA), which is now planned for submission by the end of 2010 for treatment of OIC in the chronic, non-cancer pain population.

**Intravenous RELISTOR.** We and Wyeth also have had in development an intravenous formulation of RELISTOR for the management of post-operative ileus (POI), a temporary impairment of the gastrointestinal tract function. Results from two phase 3 clinical trials of this formulation showed that treatment did not achieve primary or secondary end points. Recent results from a third phase 3 trial evaluating an intravenous formulation of RELISTOR in patients following abdominal hernia repair have confirmed these earlier findings.

**Oral RELISTOR.** Wyeth is leading development of an oral formulation of RELISTOR for the treatment of OIC in patients with chronic, non-cancer pain. We and Wyeth are evaluating information from optimization studies of a formulation of this product candidate to determine the next stages of development.

**Collaborative Marketing and Development Agreements.** Under our Collaboration with Wyeth, we share responsibilities for developing and obtaining marketing approval of RELISTOR. Wyeth is responsible for commercializing all formulations of RELISTOR worldwide other than Japan, where we have licensed the rights to the subcutaneous formulation of RELISTOR to Ono. We have an option, under certain circumstances, to co-promote with Wyeth the sale of any or all of the formulations of RELISTOR in

the United States. Under the Wyeth Collaboration, we are entitled to receive, in addition to royalties on net sales, payments as developmental and commercialization milestones for RELISTOR are achieved and reimbursement by Wyeth for expenses we incur in connection with the development of RELISTOR under an agreed-upon development plan and budget. Manufacturing expenses for RELISTOR are funded by Wyeth.

Under our exclusive license agreement with Ono, in November 2008 we received from Ono an upfront payment of \$15.0 million, and are entitled to receive potential development milestones of up to \$20.0 million, commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. Ono also 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. See *Progenics' Licenses – Wyeth* and *– Ono Pharmaceutical*, below. Some of our rights to RELISTOR arise under a license from the University of Chicago. See *Progenics' Licenses – University of Chicago*, below.

## **Virology**

**HIV.** An estimated 33 million people worldwide are infected with HIV, which causes a slowly progressing deterioration of the immune system resulting in AIDS. Although the majority of infected people reside in sub-Saharan Africa, the current commercial market is generally limited to the U.S. and Europe, where it is estimated that over two million people are infected.

HIV specifically infects cells that have the CD4 receptor on their surface, binding to that receptor and commandeering the cell's reproductive machinery to create thousands of copies of itself (viral replication). Cells presenting the CD4 receptor include critical components of the human immune system such as T-lymphocytes, monocytes, macrophages and dendritic cells, and HIV's devastating effects are predominantly due to dysfunction and destruction of these cells resulting from HIV infection. Our scientists and their collaborators have made important discoveries in understanding how HIV enters human cells and initiates viral replication.

Five classes of products have received marketing approval from the FDA for the treatment of HIV infection and AIDS. Reverse transcriptase and protease inhibitors inhibit two different viral enzymes required for HIV to replicate once it has entered the cell. (Nucleoside and non-nucleoside reverse transcriptase inhibitors are considered as different classes by researchers and prescribers alike and have non-overlapping resistance profiles.) Integrase inhibitors inhibit the enzyme that facilitates integration of HIV genetic material into the chromosomal DNA of the cell. Entry inhibitors interrupt the viral life cycle at an earlier point, namely before HIV can bind to and transfer its genetic material into certain immune system cells in order to initiate the viral replication process.

The current standard of HIV care is a regimen of protease and reverse transcriptase inhibitor therapies, known as combination therapy, which slows the progression of disease but is not a cure. HIV's rapid mutation rate results in the development of viral strains that are resistant to these and other inhibitors, a process that is accelerated by inconsistent dosing that leads to lower drug levels and permits viral replication. In addition, many of these currently approved drugs often produce toxic side effects.

Viral entry inhibitors, such as our drug candidate **PRO 140**, represent the newest class of drugs for HIV patients. Our scientists, in collaboration with researchers at the Aaron Diamond AIDS Research Center, described in an article in *Nature* in 1996 the discovery of a co-receptor for HIV on the surface of human immune system cells used for HIV entry. After HIV binds to the CD4 receptor, it then binds to the CCR5 co-receptor, enabling fusion of the virus with the cell membrane, facilitating entry of the viral genetic information into the cell and subsequent viral replication. Our PRO 140 program is based on blocking binding of HIV to the CCR5 co-receptor. Further work by other scientists has established the existence of a second co-receptor, CXCR4, which is considered to be less ubiquitous for HIV-1 viral entry. Some strains of HIV use the CXCR4 co-receptor as a portal of entry either exclusively or in addition to CCR5. CCR5 viral-entry inhibitors, such as PRO 140, are active in blocking infection in HIV patients whose virus uses the CCR5 portal, but do not block the entry of virus that uses the CXCR4 portal.

PRO 140 is a humanized monoclonal antibody designed to block HIV infection by inhibiting the virus' ability to bind to and enter immune system cells and initiate the viral replication process. PRO 140 targets a distinct site on the co-receptor CCR5. At therapeutic concentrations tested to date, PRO 140's binding to CCR5 does not appear to interfere with the co-receptor's normal function in the body's inflammatory response. PRO 140 has been granted "Fast Track" status from the FDA, which facilitates development and expedites regulatory review of drugs intended to address unmet medical needs for serious or life-threatening conditions. We have recently selected for further clinical development the subcutaneous form of PRO 140 for the treatment of HIV infection, with the goal of developing a long-acting, self-administered therapy. The results from a recently completed clinical study indicate that subcutaneous PRO 140 has the potential to be administered weekly.

**ProVax** is our vaccine product candidate under development for the prevention of HIV infection or as a therapeutic treatment for HIV-positive individuals. We are currently performing research and development on ProVax in collaboration with the Weill Medical College of Cornell University. We have funded this project via a National Institutes of Health contract which NIH has committed to fund only through 2008. We have applied for continued funding for this program and are funding it with our own resources pending a decision on that application.

ProVax contains critical surface proteins whose form closely mimics the structures found on HIV. In a pre-clinical model, ProVax stimulated the production of specific HIV neutralizing antibodies. When tested in the laboratory, these antibodies inactivated certain strains of HIV isolated from infected individuals. The vaccine-stimulated neutralizing antibodies were observed to bind to the surface of the virus, rendering it non-infectious. Such neutralizing antibodies against HIV have been difficult to induce with vaccines currently in development.

**HCV.** We have selected a proprietary orally-available small-molecule drug candidate, designated **PRO 206**, for clinical development as a treatment of HCV infection, the most common blood-borne infection in the U.S. and a major cause of chronic liver disease. According to the U.S. Centers for Disease Control and Prevention, an estimated 4.1 million Americans (1.6%) have been infected with HCV, of whom 3.2 million are chronically infected, and there are an estimated 35,000 new HCV infections in the U.S. each year. It is estimated that more than 170 million people worldwide are infected with HCV. Chronic hepatitis C, which is under-recognized due to slow, asymptomatic progression, can lead to cirrhosis and ultimately liver failure and, as a result, is now the most common reason for liver transplantation and the leading cause of liver cancer in the U.S.

Our HCV treatment candidate, an orally available viral-entry inhibitor designed to prevent HCV from entering and infecting healthy liver cells, has exhibited favorable results in pre-clinical and *in vitro* studies. We are conducting preclinical development activities in preparation for filing an IND for PRO 206.

## Oncology

**Prostate cancer** is a common cancer affecting men in the U.S. and a leading cause of cancer deaths in men each year. The National Cancer Institute estimates that, based on rates from 2002-2004, one in six men will be diagnosed with cancer of the prostate during their lifetime. The American Cancer Society estimated that 186,320 new cases of prostate cancer would be diagnosed and that 28,660 men would die from the disease in 2008 in the U.S.

Conventional therapies for prostate cancer include radical prostatectomy, radiation, hormone therapies and chemotherapy. These treatments may have or increase the risk of a variety of side effects, including impotence, incontinence, high cholesterol levels and increased blood-clot risk. Hormone therapy and chemotherapy are generally not intended to be curative and are not actively used to treat localized, early-stage prostate cancer.

Through our wholly owned subsidiary, PSMA Development Company LLC (PSMA LLC), we conduct research and development programs relating to antibody and vaccine therapies directed against prostate specific membrane antigen, or **PSMA**, a protein that is abundantly expressed on the surface of prostate cancer cells as well as cells in the newly formed blood vessels of many other solid tumors. Our fully human monoclonal ADC 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. We believe a PSMA-directed therapy may have application in prostate cancer and solid tumors of other types of cancer. In September 2008, we initiated a phase 1 dose-escalation clinical study to assess PSMA ADC's safety, tolerability and initial clinical activity in patients with progressive, castrate-resistant prostate cancer.

We have initiated clinical study of a therapeutic vaccine utilizing viral vectors designed to deliver the PSMA gene to certain immune system cells in order to generate potent and specific immune responses to prostate cancer cells. In pre-clinical studies, this vaccine generated a potent dual response against PSMA, by both antibodies and killer T-cells, the two principal mechanisms used by the immune system to eliminate abnormal cells. We are also developing a vaccine combining the PSMA cancer antigen (recombinant soluble PSMA) with an immune stimulant to induce an immune response against prostate cancer cells.

## Licenses

Progenics and PSMA LLC are parties to license agreements under which we have in- and/or out-licensed rights to use certain technologies and materials. These licenses 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. Our costs in defending patent rights, both our own and those we license, have historically not been material. Set forth below is a summary of the more significant of these licenses.

### *Progenics' Licenses*

- Under the Wyeth Collaboration Agreement, we granted to **Wyeth** an exclusive, worldwide license to develop and commercialize RELISTOR. In October 2008, we reacquired the rights to all formulations of RELISTOR in Japan from Wyeth, and out-licensed the rights to subcutaneous RELISTOR in Japan to Ono (see discussion below). We are responsible for developing the subcutaneous and intravenous formulations of RELISTOR in the U.S. until they receive regulatory approval, while Wyeth is responsible for these formulations outside

the U.S. other than Japan. Wyeth is also responsible for developing the oral formulation of RELISTOR, and any other formulation the companies may determine to pursue, within the U.S. and the rest of its territory. We own the rights to all formulations, including the oral formulation, in Japan, where we have given Ono an exclusive license to the subcutaneous formulation and have granted Ono an option to acquire licenses on other formulations in Japan. We own all U.S. regulatory filings and approvals relating to the subcutaneous and intravenous formulations, and Wyeth owns all such filings and approvals for the oral formulation. Wyeth also owns all regulatory filings and approvals for all formulations outside the U.S. other than in Japan, where Ono owns the filings and approvals relating to subcutaneous RELISTOR and we retain the rights to other formulations.

Costs for the development of RELISTOR incurred by Wyeth or us are paid by Wyeth. We are reimbursed for our out-of-pocket development costs by Wyeth and receive reimbursement for our efforts based on our employees devoted to them, all subject to Wyeth's audit rights and possible reconciliation as provided in the Collaboration Agreement. As part of its commercialization responsibilities in its territory, Wyeth is obligated to pay all commercialization costs, including manufacturing costs, and retains all proceeds from sales of products, subject to royalties and other amounts payable by Wyeth to us. Decisions with respect to commercialization of any products developed under the Collaboration Agreement are made solely by Wyeth.

The Collaboration Agreement establishes Joint Steering and Joint Development Committees, each with an equal number of representatives from both Wyeth and us. The JSC is responsible for coordinating the companies' key activities, while the JDC oversees, coordinates and expedites the development of RELISTOR by Wyeth and us. A Joint Commercialization Committee, composed of company representatives in number and function according to our respective responsibilities, facilitates open communication between Wyeth and us on commercialization matters.

We have an option to co-promote in the U.S. any of the products developed under the Collaboration Agreement, subject to certain conditions. The extent of our co-promotion activities and the fee that we will be paid by Wyeth for our activities will be established if, as and when we exercise our option. Wyeth will record all sales of products worldwide (including those sold by us, if any, under a co-promotion agreement). Wyeth may terminate any co-promotion agreement if a top-15 pharmaceutical company acquires control of us. Wyeth has also agreed to certain "standstill" limitations, expiring in June 2009, regarding its ability to purchase our equity securities and to solicit proxies.

The Wyeth Collaboration extends, unless terminated earlier, on a country-by-country and product-by-product basis, until the last-to-expire royalty period for any product. We may terminate the Wyeth Collaboration at any time upon 90 days written notice to Wyeth upon Wyeth's material uncured breach (30 days in the case of breach of a payment obligation). Wyeth may, with or without cause, terminate the Collaboration effective on or after the second anniversary of the first U.S. commercial sale of RELISTOR, by providing Progenics with at least 360 days prior written notice. Wyeth may also terminate the agreement (i) upon 30 days written notice following one or more specified serious safety or efficacy issues that arise and (ii) upon 90 days written notice of a material uncured breach by Progenics. Upon termination of the Wyeth Collaboration, the ownership of the license we granted to Wyeth will depend on which party initiates the termination and the reason for the termination.

- We have exclusive rights to develop and commercialize methylnaltrexone, the active ingredient of RELISTOR, under license from the **University of Chicago**. We have the obligation under the license to make milestone and royalty payments to the University in connection with that development and commercialization that in general extend to the expiration of the last-to-expire patent.

- Under an exclusive License Agreement, we have licensed to **Ono Pharmaceutical** the rights to subcutaneous RELISTOR in Japan. Under the Ono License, Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono is to own the subcutaneous filings and approvals relating to RELISTOR in Japan. We have received a \$15.0 million upfront payment from Ono, and are entitled to receive up to an additional \$20.0 million, payable upon achievement of 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. Supervision of and consultation with respect to Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer-related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them. The Ono License contains, among other terms, provisions which allow termination by either party upon the occurrence of certain events.

- **Protein Design Labs** (now **Facet Biotech Corporation**) humanized a murine monoclonal antibody developed by us (humanized PRO 140) and granted us related licenses under patents and patent applications, in addition to know-how. In general, these licenses are fully paid after the latest of (i) the tenth anniversary of the first commercial sale of a product developed thereunder, (ii) expiration of the last-to-expire patent or (iii) the tenth anniversary of the latest filed pending patent application. Pending U.S. and international patent applications and patent-term extensions may extend the period of our license rights when and if they are allowed,

issued or granted. We may terminate the license on 60 days prior written notice, and either party may terminate on 30 days prior written notice for an uncured material breach (ten days for payment default). As of December 31, 2008, we have paid Facet's predecessors \$5.2 million, and if all milestones are achieved, we will be obligated to pay an additional approximately \$2.0 million. We are also required to pay annual maintenance fees of \$150,000 and royalties on sales of products developed under the license.

- We have a letter agreement with the **Aaron Diamond AIDS Research Center** pursuant to which we have the exclusive right to pursue the commercial development, directly or with a partner, of products related to HIV based on patents jointly owned by ADARC and us.

- For a number of years, we have been party to a license agreement with **Columbia University** under which we obtained rights to technology and materials for a program we have since terminated. As of December 31, 2008, we had paid Columbia a total of \$890,000 under this license agreement, including \$25,000 in royalties. In January 2009, we and Columbia agreed to terminate and amend certain rights granted in this license in exchange for a one-time payment of \$300,000, which was accrued as of December 31, 2008. Under this new arrangement, we retain rights to certain technology for sales of reagents and other purposes, subject to royalties. We do not expect this new agreement will be material to us.

- For a number of years, we were party to a license and supply agreement with **Aquila Biopharmaceuticals, Inc.**, a wholly owned subsidiary of **Antigenics Inc.**, for a program we have since terminated. In November 2008, the agreement was terminated and a portion of the contingent shares issued to Aquila in connection with the agreement have since been cancelled. We do not believe this matter will have any material effect on us.

### ***PSMA LLC Licenses***

- PSMA LLC has a worldwide exclusive licensing agreement with **Abgenix** (now **Amgen Fremont, Inc.**) to use its XenoMouse<sup>®</sup> technology for generating fully human antibodies to PSMA LLC's PSMA antigen. PSMA LLC is obligated to make payments under this license upon the occurrence of defined milestones associated with the development and commercialization program for products incorporating an antibody generated utilizing the XenoMouse technology. As of December 31, 2008, PSMA LLC has paid to Abgenix \$850,000 under this agreement. If PSMA LLC achieves certain milestones specified under the agreement, it will be obligated to pay Abgenix up to an additional \$6.25 million. In addition, PSMA LLC is required to pay royalties based upon net sales of antibody products, if any. This agreement may be terminated, after an opportunity to cure, by Abgenix for cause upon 30 days prior written notice. PSMA LLC has the right to terminate this agreement upon 30 days prior written notice. If not terminated early, this agreement continues until the later of the expiration of the XenoMouse technology patents that may result from pending patent applications or seven years from the first commercial sale of the products.

- PSMA LLC also has a worldwide exclusive license agreement with **AlphaVax Human Vaccines** to use its AlphaVax Replicon Vector system to create a therapeutic prostate cancer vaccine incorporating PSMA LLC's proprietary PSMA antigen. PSMA LLC is obligated to make payments under the license upon the occurrence of certain milestones associated with the development and commercialization program for products incorporating AlphaVax's system. As of December 31, 2008, PSMA LLC has paid to AlphaVax \$1.7 million under this agreement. If PSMA LLC achieves certain milestones specified under the agreement, it will be obligated to pay AlphaVax up to an additional \$5.3 million. In addition, PSMA LLC is required to pay annual maintenance fees of \$100,000 until the first commercial sale and royalties based upon net sales of any products developed using AlphaVax' system. This agreement may be terminated, after an opportunity to cure, by AlphaVax under specified circumstances, including PSMA LLC's failure to achieve milestones; the consent of AlphaVax to revisions to the milestones due dates may not, however, be unreasonably withheld. PSMA LLC has the right to terminate the agreement upon 30 days prior written notice. If not terminated early, this agreement continues until the later of the expiration of the patents relating to AlphaVax's system or seven years from the first commercial sale of the products developed using that system. Pending U.S. and international patent applications and patent-term extensions may extend the period of our license rights when and if they are allowed, issued or granted.

- PSMA LLC has a collaboration agreement with **Seattle Genetics, Inc.**, under which SGI has granted PSMA LLC an exclusive worldwide license to its proprietary ADC technology. Under the license, PSMA LLC has the right to use this technology to link chemotherapeutic agents to PSMA LLC's monoclonal antibodies that target prostate specific membrane antigen. The ADC technology is based, in part, on technology licensed by SGI from third parties. PSMA LLC is responsible for research, product development, manufacturing and commercialization of all products under the SGI agreement. PSMA LLC may sublicense the ADC technology to a third party to manufacture ADCs for both research and commercial use. Under the agreement, PSMA LLC is obligated to make maintenance payments, additional payments aggregating up to \$14.0 million upon the achievement of certain milestones 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. PSMA LLC may terminate the SGI agreement upon advance written notice to SGI. SGI may terminate the agreement if PSMA LLC fails to cure a breach of an SGI in-license within a specified time period after

written notice. In addition, either party may terminate the SGI agreement after written notice upon an uncured breach or in the event of bankruptcy of the other party. As of December 31, 2008, PSMA LLC has paid to SGI approximately \$3.6 million under this agreement, including \$1.0 million in milestone payments.

## **Patents and Proprietary Technology**

Our policy is to protect our proprietary technology, and we consider the protection of our rights to be important to our business. In addition to seeking U.S. patent protection for many of our inventions, we generally file patent applications in Canada, Japan, European countries that are party to the European Patent Convention and additional foreign countries on a selective basis in order to protect the inventions that we consider to be important to the development of our foreign business. Generally, patents issued in the U.S. are effective:

- if the patent application was filed prior to June 8, 1995, for the longer of 17 years from the date of issue or 20 years from the earliest asserted filing date; or
- if the application was filed on or after June 8, 1995, for 20 years from the earliest asserted filing date.

In addition, in certain instances, the patent term can be extended up to a maximum of five years to recapture a portion of the term during which the 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.

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 generally require our employees, consultants and corporate partners who have access to our proprietary information to sign confidentiality agreements.

Our patent portfolio relating to our proprietary technologies in the supportive care, virology and cancer areas is currently comprised, on a worldwide basis, of 171 patents that have been issued and 254 pending patent applications, which we either own directly or of which we are the exclusive licensee. Our issued patents expire on dates ranging from 2010 through 2026. Patent-term extensions and pending patent applications may extend the period of patent protection afforded our products in development.

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 methylnaltrexone and other peripheral opioid antagonists, PSMA or related compounds, CCR5 monoclonal antibodies and HCV viral entry inhibitors, and of patents and applications held or filed by others in those areas. While the validity of issued patents, patentability of claimed inventions in pending applications and applicability of any of them to our programs are uncertain, patent rights asserted against us could adversely affect our ability to commercialize or collaborate with others regarding our products.

The research, development and commercialization of a biopharmaceutical product often present alternative development and optimization routes at various stages in the development process. Preferred routes cannot be identified with certainty at the outset because they will depend upon subsequent discoveries and test results. There are numerous third-party patents in our field, and it is possible that to pursue the preferred development route of one or more of our product candidates we will need to obtain a license under a patent, which could decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, pursuit of a less desirable development route or termination of the entire program may be necessary.

## **Government Regulation**

Progenics and its product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries. Pharmaceutical regulation currently is a topic of substantial interest in lawmaking and regulatory bodies in the U.S. and internationally, and numerous proposals exist for changes in FDA and non-U.S. regulation of pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, recordkeeping, 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.

**FDA Regulation.** FDA approval of our product candidates, including a review of the manufacturing processes and facilities used to produce them, are required before they 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 the FDA and effectiveness of an IND 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 product's pharmacology and toxicology and to identify safety problems that would preclude testing in humans. Products must generally be manufactured according to current Good Manufacturing Practices, and pre-clinical safety tests must be conducted by laboratories that comply with FDA good laboratory practices regulations.

Results of pre-clinical tests are submitted to the FDA as part of an **IND (Investigational New Drug)** application, 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. We cannot assure you that an IND submission by us will result in FDA authorization to commence clinical trials.

**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. 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.

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. Our analysis of the results of our clinical studies is subject to

review and interpretation by the FDA, which may differ from our analysis. We cannot assure you that our data or our interpretation of data will be accepted by the FDA. In any event, the FDA must deny an NDA or BLA if applicable regulatory requirements are not ultimately satisfied. In addition, we may encounter delays or rejections based upon changes in applicable law or FDA policy during the period of product development and FDA regulatory review. 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. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

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 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. New government requirements may be established that could delay or prevent regulatory approval of our products under development.

**Regulation Outside the U.S.** Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable government regulatory authorities in foreign countries 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 we must satisfy to obtain regulatory approval by governmental agencies in other countries prior to commercialization of our products there can be rigorous, costly and uncertain, and there can be no assurance that approvals will be granted on a timely basis or at all. We do not currently have any facilities or personnel outside of the U.S.

In the European Union, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States. 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 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 Wyeth have not examined in detail. If the particular product is manufactured in the U.S., we must also comply with FDA and other U.S. export provisions.

In most countries outside the U.S., coverage, pricing and reimbursement approvals are also required. There can be no assurance that the resulting pricing of our products would be sufficient to generate an acceptable return to us.

**Other Regulation.** In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and various other present and potential future federal, state or local regulations. Our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our safety procedures for storing, handling, using and disposing of such materials comply with the standards prescribed by applicable regulations, we cannot completely eliminate the risk of accidental contaminations or injury from these materials. In the event of such an accident, we could be held liable for any legal and regulatory violations as well as damages that result. Any such liability could have a material adverse effect on Progenics.

## **Manufacturing**

Wyeth is responsible for the supply of RELISTOR for clinical-trial and commercial requirements under the Collaboration Agreement, and Ono has similar obligations under the Ono License.

We have contracted with a third-party contract manufacturing organization (CMO) to produce PRO 140 for our ongoing clinical trials. We currently manufacture clinical trial supplies of our PSMA monoclonal antibody in our biologics pilot production facilities in Tarrytown, New York, utilizing two 150-liter bioreactors, and have engaged CMOs for other portions of the PSMA-ADC manufacturing process. We expect our manufacturing capacity will not be sufficient for all of our late-stage clinical trials or commercial-scale requirements. If we are unable to arrange for satisfactory CMO services, or otherwise determine to acquire additional manufacturing capacity, we will 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 plan to market products for which we obtain regulatory approval through co-marketing, co-promotion, licensing and distribution arrangements with third-party collaborators. We may also consider contracting with a third-party professional pharmaceutical detailing and sales organizations to perform promotional and/or medical-scientific support functions for our products. Under the terms of our Collaboration Agreement with Wyeth, Wyeth granted us an option to enter into a co-promotion agreement to co-promote any of the RELISTOR products developed under the Collaboration, subject to certain conditions. The extent of our co-promotion activities and the fee that we will be paid by Wyeth for these activities will be established if, as and when we exercise our option. Wyeth will record all sales of products worldwide (including those sold by us, if any, under a co-promotion agreement).

## 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 will 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 under development may not compete successfully with existing products or products under development by other companies, universities and other institutions. Our competitors may succeed in obtaining FDA marketing approval for products more rapidly than we do. 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. Accordingly, we believe that the speed with which we develop products, complete the clinical trials and approval processes and ultimately supply commercial quantities of the products to the market will be an important competitive factor.

**RELISTOR** is the first FDA-approved product for any indication involving OIC. We are, however, aware of products in pre-clinical or clinical development that target the side effects of opioid pain therapy. Nektar Therapeutics has completed a phase 2 study in patients with OIC of an oral peripheral opioid antagonist. Sucampo Pharmaceuticals, Inc., in collaboration with Takeda Pharmaceutical Company Limited, is currently conducting phase 3 pivotal clinical trials of AMITIZA<sup>®</sup> (lubiprostone) for the treatment of opioid-induced bowel dysfunction. In addition, Adolor Corporation markets ENTEREG<sup>®</sup> (alvimopan) for the treatment of post-operative ileus, and in Europe Mundipharma International markets TARGIN<sup>®</sup> (oxycodone/naloxone, a combination of an opioid and a systemic opioid antagonist).

Five classes of products have been approved for marketing by the FDA for the treatment of **HIV infection and AIDS**. These drugs have shown efficacy in reducing the concentration of HIV in the blood and prolonging asymptomatic periods in HIV-positive individuals. All have been required to show efficacy in conjunction with other agents, which we have not demonstrated for PRO 140. We are aware of several competitors that are marketing or developing small-molecule viral-entry-inhibitor treatments directed against CCR5 for HIV infection, including Pfizer's SELZENTRY<sup>™</sup> (maraviroc) tablets and Trimeris' FUZEON<sup>®</sup>, but we are unaware of any antibody-based viral-entry inhibitor treatments at PRO 140's stage of clinical development. We are also aware of various HCV drugs in pre-clinical or clinical development.

**HCV infection** is most commonly treated by a combination of interferon and ribavirin. Seroconversion and/or sustained response to such therapies ranges from 30-50%. Tolerability and route of administration for this therapy may compromise a patient's ability to persist with treatment for the 48-72 months sometimes required. We are aware of several competitors who are developing small molecule HCV antivirals, including viral-entry inhibition-based treatments.

Radiation and surgery are two principal traditional forms of treatment for **prostate cancer**, to which our PSMA-based development efforts are directed. If the disease spreads, hormone (androgen) suppression therapy is often used to slow the cancer's progression. This form of treatment, however, can eventually become ineffective. We are aware of several competitors who are developing alternative treatments for castrate-resistant prostate cancer, some of which are directed against PSMA.

A significant amount of research in the biopharmaceutical field is also being carried out at **academic and government institutions**. An element of our research and development strategy is to in-license technology and product candidates from academic and government institutions. These institutions are becoming increasingly sensitive to the commercial value of their findings and are becoming more aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed. These institutions may also market competitive commercial products on their own or in collaboration with competitors and will compete with us in recruiting highly qualified scientific personnel. Any resulting increase in

the cost or decrease in the availability of technology or product candidates from these institutions may adversely affect our business strategy.

Competition with respect to our technologies and products is based on, among other things, (i) product efficacy, safety, reliability, method of administration, availability, price and clinical benefit relative to cost; (ii) timing and scope of regulatory approval; (iii) sales, marketing and manufacturing capabilities; (iv) collaborator capabilities; (v) insurance and other reimbursement coverage; and (vi) patent protection.

Our competitive position will also depend on our 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 will bear the risk of product liability directly. We have obtained product liability insurance coverage in the amount of \$10.0 million per occurrence, subject to a deductible and a \$10.0 million aggregate limitation. In addition, where the 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. We may not be able to continue to maintain insurance at a reasonable cost, or in adequate amounts.

### **Human Resources**

At December 31, 2008, we had 244 full-time employees, 37 of whom hold Ph.D. degrees, 7 of whom hold M.D. degrees and two of whom, including Dr. Paul J. Maddon, our Chief Executive Officer and Chief Science Officer, hold both Ph.D. and M.D. degrees. At such date, 192 employees were engaged in research and development, medical, regulatory affairs and manufacturing activities and 52 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**

Our business and operations entail a variety of serious risks and uncertainties, including those described below.

#### **Our product development programs are inherently risky.**

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. We must complete successfully clinical trials and obtain regulatory approvals for our product candidates as well as additional formulations of and indications for RELISTOR. In the Japanese market, we must rely on Ono to conduct successful clinical trials and obtain regulatory approvals. Our other research and development programs, including those related to PSMA and PRO 140, involve novel approaches to human therapeutics. 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 products.

#### **We are dependent on Wyeth and Ono to develop and commercialize RELISTOR in their respective areas, exposing us to significant risks, including that Wyeth's announced acquisition by Pfizer may adversely affect our Collaboration.**

We are dependent upon Wyeth and Ono in their respective territories to perform and fund development, including clinical testing of RELISTOR, make related regulatory filings and manufacture and market products. Revenues from the sale of RELISTOR depend almost entirely upon the efforts of Wyeth and, in Japan, Ono. Wyeth and Ono have significant discretion in determining the efforts and resources they apply to sales of the RELISTOR products in their territories and may not be effective in marketing such products. Our business relationships with Wyeth and Ono may not be scientifically, clinically or commercially successful.

Wyeth is a large, diversified pharmaceutical company with global operations and its own corporate objectives, which may not be consistent with our best interests. In addition, Wyeth and Pfizer have recently entered a definitive agreement under which Pfizer is to acquire Wyeth. We cannot predict how a combined Pfizer and Wyeth may view the utility and attractiveness of our Collaboration. As a result of completion of this proposed acquisition or for other reasons, Wyeth or Pfizer may change its strategic focus or pursue alternative technologies in a manner that results in reduced or delayed revenues to us. We cannot predict whether a combined Pfizer and Wyeth will determine to continue, seek to change or terminate our Collaboration, or devote the same resources Wyeth currently dedicates to it. If a combined Wyeth and Pfizer were to terminate the Collaboration, we would no longer receive

milestone and royalty payments and would need to undertake development and commercialization of RELISTOR ourselves or through another collaboration or licensing arrangement. We may not learn of their plans for RELISTOR and our Collaboration unless and until the proposed transaction closes.

If our relationship with Wyeth or Ono terminates and we seek alternative arrangements with one or more other parties to develop and commercialize RELISTOR, we may not be able to enter into such an agreement with other suitable companies on acceptable terms or at all. To continue to develop and commercialize RELISTOR on our own, we would have to develop sales and marketing organization and a distribution infrastructure, neither of which we currently have. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our financial resources and profitability. A termination of our relationship with Wyeth could also seriously compromise the development program for RELISTOR and possibly our other product candidates, as we could experience significant delays and would have to assume full funding and other responsibility for further development and eventual commercialization. Any of these outcomes would result in delays in our ability to distribute RELISTOR and would increase our expenses.

Our relationships with Wyeth and Ono are multi-faceted and involve complex sharing of control over decisions, responsibilities, costs and benefits. We have had and may have future disagreements with them concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property. Both Wyeth and Ono have significantly greater financial and managerial resources than we do, which either could draw upon in the event of a dispute. Disagreements between either of them and us could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as to extensive financial and operational consequences to us, and have a material adverse effect on our business, results of operations and financial condition.

**If testing does not yield successful results, our products will not be approved.**

Regulatory approvals are necessary before product candidates can be marketed. To obtain them, we or our collaborators must demonstrate a product's safety and efficacy through extensive pre-clinical and clinical testing. Numerous adverse events may arise during, or as a result of, the testing process, such as:

- results of pre-clinical studies being inconclusive or not indicative of results in human clinical trials;
- potential products not having the desired efficacy or having undesirable side effects or other characteristics that preclude marketing approval or limit their commercial use if approved;
- after reviewing test results, we or our collaborators may abandon projects which we previously believed to be promising; and
- we, our collaborators or regulators may suspend or terminate clinical trials if we or they believe that the participating subjects are being exposed to unacceptable health risks.

Clinical testing is very expensive and can take many years. 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, such as PRO 140, PRO 206 and the PSMA product candidates, 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.

**A setback in clinical development programs could adversely affect us.**

We and Wyeth continue to conduct clinical trials of RELISTOR. If the results of these or future trials are not satisfactory, we encounter problems enrolling subjects, clinical trial supply issues or other difficulties arise, or we experience setbacks in developing drug formulations, including raw material-supply, manufacturing or stability difficulties, our entire RELISTOR development program could be adversely affected, resulting in delays in trials or regulatory filings for further marketing approval. Conducting additional clinical trials or making significant revisions to our clinical development plan would lead to delays in regulatory filings. If clinical trials indicate a serious problem with the safety or efficacy of a RELISTOR product, Wyeth may terminate the Collaboration Agreement or stop development or commercialization of affected products. Since RELISTOR is our only approved product, any setback of these types could have a material adverse effect on our business, results of operations and financial condition.

Ono must conduct clinical trials with Japanese patients to obtain regulatory approval in Japan. We have not tested RELISTOR in Japanese patients, and there can be no assurance that clinical trials of RELISTOR in Japanese patients will yield results adequate for regulatory approval in Japan.

We are conducting or planning clinical trials of PRO 140, PSMA ADC and prostate cancer vaccine candidates. If the results of our future clinical studies of PRO 140 or PSMA ADC or the pre-clinical and clinical studies involving the PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved. Because our vaccine product candidates may be deemed to involve gene therapy, a relatively new technology that has not been extensively tested in humans, regulatory requirements applicable to them may be unclear, or subject to substantial regulatory review that delays the development and approval process generally.

**We have a history of operating losses, and we may never be profitable.**

We have incurred substantial losses since our inception. As of December 31, 2008, we had an accumulated deficit of \$298.7 million. We have derived no significant revenues from product sales or royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur additional operating losses in the future, which could increase significantly as we expand our clinical trial programs and other product development efforts.

Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval for and then commercializing our products, 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 products under development are commercialized.

**We are likely to need additional financing, but our access to capital funding is uncertain.**

As of December 31, 2008, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$141.4 million. During the year ended December 31, 2008, we had a net loss of \$44.7 million and cash used in operating activities was \$28.3 million.

Although our spending on RELISTOR has been significant during 2007 and 2008, our net expenses for RELISTOR have been reimbursed by Wyeth under the Collaboration Agreement. We expect our spending on RELISTOR will decline in 2009 and thereafter, which will result in less reimbursement by Wyeth.

With regard to other product candidates, we expect to continue to incur significant development expenditures, and do not have committed external sources of funding for most of these projects. These 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, securities issuances or government grants or contracts. We cannot predict when we will need additional funds, how much we will need or if additional funds will be available, 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 or other opportunities which we cannot predict, and many of which are outside our control.

Our access to capital funding is always uncertain. Recent turmoil in the international capital markets has exacerbated this uncertainty. Despite previous experience, 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 the future success of our business.

If we raise funds by issuing and selling securities, it may be on terms that are not favorable to existing stockholders. If we raise funds by selling equity securities, current stockholders will be diluted, and new investors could have rights superior to existing stockholders. Raising funds by selling debt securities often entails significant restrictive covenants and repayment obligations.

A substantial portion of our cash and cash equivalents are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee programs. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale and are predominantly not guaranteed. These investments, while rated investment grade by the Standard & Poor's and Moody's rating agencies and predominantly having scheduled maturities in the first three quarters of 2009, are heavily concentrated in the U.S. financial sector, which continues to be under extreme stress.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy

orders. As a result, at December 31, 2008, we continue to hold approximately \$4.1 million of auction rate securities which, in the event of auction failure, have been reset according to the contractual terms in the governing instruments. To date, we have received all scheduled interest payments on these securities. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid, or a buyer outside the auction process emerges.

We monitor markets for our investments, but cannot guarantee that additional losses will not be required to be recorded. 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.

**Our clinical trials could take longer than we expect.**

Forecasts we publicly announce of commencement and completion times for clinical trials may not be accurate. For example, we have experienced delays in our RELISTOR clinical development program in the past as a result of slower than anticipated enrollment. These delays may recur. Delays can be caused by, among other things:

- deaths or other adverse medical events involving subjects in our clinical trials;
- regulatory or patent issues;
- interim or final results of ongoing clinical trials;
- failure to enroll clinical sites as expected;
- competition for enrollment from clinical trials conducted by others in similar indications;
- scheduling conflicts with participating clinicians and clinical institutions;
- disagreements, disputes or other matters arising from collaborations;
- our inability to obtain additional funding when needed; and
- manufacturing problems.

We have limited experience in conducting clinical trials, and we rely on others to conduct, supervise or monitor some or all aspects of some of our 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. Under our agreement with Wyeth relating to RELISTOR, Wyeth has the responsibility to conduct some of the clinical trials for that product, including all trials outside of the United States other than Japan, where Ono has the responsibility for clinical trials. We have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

These events may impair investors' confidence in our ability to develop products and our stock price may decline.

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

We and our products 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. If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences. We cannot guarantee that approvals of proposed products, 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.

**Our product candidates may not obtain regulatory approvals needed for marketing, and may face challenges after approval.**

None of our product candidates other than RELISTOR 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 the marketing approval from the FDA or any other regulatory authority necessary for commercialization.

Even if our products receive regulatory approval:

- they 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 “black box” or other warnings that adversely affect their commercial success;
- approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are relatively less financially advantageous to us than approval of greater or different scope, or subject to an FDA-imposed Risk Evaluation and Mitigation Strategy (REMS) that limits the sources from and conditions under which they may be dispensed;
- we or our collaborators might be required to undertake post-marketing trials to verify the product’s efficacy or safety;
- 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 or our collaborators might experience manufacturing problems, which could have the same, similar or other consequences; and
- we and our collaborators will be subject to ongoing FDA obligations and continuous regulatory review.

If products fail to receive marketing approval or lose previously received approvals, our financial results would be adversely affected.

**Even if our products obtain marketing approval, they might not be accepted in the marketplace.**

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. 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. For pharmaceuticals administered in an institutional setting, the ability of the institution to be adequately reimbursed could also play a significant role in demand for our products. Even if our products obtain marketing approval, they may not achieve market acceptance. If any of our products do not achieve market acceptance, we will likely lose our entire investment in that product.

**Marketplace acceptance will depend in part on competition in our industry, which is intense.**

The extent to which any of our products achieves market acceptance will depend on competitive factors. Competition in our industry is intense, and it is accentuated by the rapid pace of technological development. There are products currently in the market that will compete with the products that we are developing, including AIDS drugs and chemotherapy drugs for treating cancer. There are also products in pre-clinical or clinical development that target the side effects of opioid pain therapy, and Adolor Corporation markets ENTEREG<sup>®</sup> (alvimopan) for the treatment of post-operative ileus, which could compete with RELISTOR. 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. If our product candidates receive marketing approval but cannot compete effectively in the marketplace, our operating results and financial position would suffer. Competition with respect to our technologies and products is based on, among other things, (i) product efficacy, safety, reliability, method of administration,

availability, price and clinical benefit relative to cost; (ii) timing and scope of regulatory approval; (iii) sales, marketing and manufacturing capabilities; (iv) collaborator capabilities; (v) insurance and other reimbursement coverage; and (vi) patent protection. Competitive disadvantages in any of these factors could materially harm our business and financial condition.

**Competing products may adversely affect our products.**

We are aware that Adolor Corporation, in collaboration with GlaxoSmithKline, received FDA approval in May 2008 for ENTEREG<sup>®</sup> (alvimopan), an oral form of an opioid antagonist, for postoperative ileus, “to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis.” We are also aware that Sucampo Pharmaceuticals, Inc., in collaboration with Takeda Pharmaceutical Company Limited, is currently conducting phase 3 pivotal clinical trials of AMITIZA<sup>®</sup> (lubiprostone) for the treatment of opioid-induced bowel dysfunction, and that Nektar Therapeutics has completed a phase 2 study of an oral once-a-day peripheral opioid antagonist in patients with OIC. In Europe, we are aware that Mundipharma International markets TARGIN<sup>®</sup> (oxycodone/naloxone, a combination of an opioid and systemic opioid antagonist). Any of these drugs may achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of GSK and Takeda may impair our ability to compete effectively in the market.

In the case of PRO 140, five classes of products have been approved for marketing by the FDA for the treatment of HIV infection and AIDS. These drugs have shown efficacy in reducing the concentration of HIV in the blood and prolonging asymptomatic periods in HIV-positive individuals. All have been required to show efficacy in conjunction with other agents, which we have not demonstrated for PRO 140. We are aware of two approved drugs designed to treat HIV infection by blocking viral entry (Trimeris’ FUZEON<sup>®</sup> and Pfizer’s SELZENTRY<sup>™</sup>). We are also aware of various HCV drugs in pre-clinical or clinical development.

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

Our business strategy includes entering into collaborations with pharmaceutical and biotechnology companies to develop and commercialize product candidates and technologies. We may not be successful in negotiating additional collaborative arrangements. If we do not enter into new collaborative arrangements, we would have to devote more of our resources to clinical product development and product-launch activities, seeking additional sources of capital, and our cash burn rate would increase or we would need to take steps to reduce our rate of product development.

**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.

**We have limited manufacturing capabilities, which could adversely affect our ability to commercialize products.**

We have limited manufacturing capabilities, which may result in increased costs of production or delay product development or commercialization. In order to commercialize our product candidates successfully, we or our collaborators must be able to manufacture 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 products may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available to us on a timely basis or at all, our clinical trials could be seriously delayed, since these materials are time consuming to manufacture and cannot be readily obtained from third-party sources.

We operate pilot-scale manufacturing facilities for the production of vaccines and recombinant proteins. These facilities will not be sufficient for late-stage clinical trials for these types of product candidates or commercial-scale manufacturing. We may be required to expand further our manufacturing staff and facilities, obtain new facilities or contract with corporate collaborators or other third parties to assist with production.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are

extensive. We may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our clinical trials or commercial scale manufacturing.

We have entered into arrangements with third parties for the manufacture of some of our product candidates. Our third-party sourcing strategy may not result in a cost-effective means for manufacturing products. In employing third-party manufacturers, we do not control many aspects of the manufacturing process, including compliance with the FDA's current Good Manufacturing Practices and other regulatory requirements. We 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.

**We are dependent on our patents and other intellectual property rights. The validity, enforceability and commercial value of these rights are highly uncertain.**

Our success is dependent in part upon obtaining, maintaining and enforcing patent and other intellectual property rights. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. Accordingly, patent applications owned by or licensed to us may not result in patents being issued. We are aware of others who have patent applications or patents containing claims similar to or overlapping those in our patents and patent applications. We do not expect to know for several years the relative strength or scope of our patent position. Patents that we own or license may not enable us to preclude competitors from commercializing drugs, and consequently may not provide us with any meaningful competitive advantage.

We own or have licenses to several issued patents. The issuance of a patent, however, is not conclusive as to its validity or enforceability, which can be challenged in litigation. Our patents may be successfully challenged. 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.

Most of our product candidates, including RELISTOR, PRO 140 and our PSMA and HCV program products, incorporate to some degree intellectual property licensed from third parties. 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.

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 by us, either in the first instance or if the licensor chooses not to do so, we must usually bear the cost of doing so. Under the Wyeth Collaboration Agreement, Wyeth has the right, at its expense, to defend and enforce the RELISTOR patents licensed to Wyeth by us. With respect to Japan, Ono has certain limited rights to prosecute, maintain and enforce relevant intellectual property. With most of our in-licenses, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under specified circumstances.

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.

**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 methylnaltrexone and other peripheral opioid antagonists, PSMA or related compounds and CCR5 monoclonal

antibodies 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.

The research, development and commercialization of a biopharmaceutical often involve alternative development and optimization routes, which are presented at various stages in the development process. The preferred routes cannot be predicted at the outset of a research and development program because they will depend on subsequent discoveries and test results. 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. 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 in part 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 products. 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 is 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 depend on Wyeth and Ono, respectively, for the commercialization and development of RELISTOR. We may not be able to maintain these relationships or establish new ones 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.

**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, significant investment, time and managerial resources will be required to build the commercial infrastructure required to market, sell and support a pharmaceutical product. Should we choose to commercialize any 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 our 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 our products. Under our license and co-development agreement with Wyeth, Wyeth is responsible for commercializing RELISTOR. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of our other products, 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.

**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. In particular, the loss of Dr. Maddon could cause our management and operations to suffer. Our employment agreement with Dr. Maddon is effective on a year-to-year basis, subject to automatic renewal unless either party terminates. Employment agreements do not assure the continued employment of an employee. We maintain key-man life insurance on Dr. Maddon in the amount of \$2.5 million.

Competition for qualified employees among companies in the biopharmaceutical industry is intense. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we may be required to expand substantially our personnel, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and marketing. We may not be successful in hiring or retaining qualified personnel.

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

We currently obtain 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 other suppliers. Wyeth may not be able to fulfill its manufacturing obligations for RELISTOR, either on its own or through third-party suppliers. 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 or capability to manufacture sufficient quantities of these products to meet our needs if our suppliers are unable or unwilling to do so. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

**A substantial portion of our funding comes from federal government grants and research contracts. We cannot rely on these grants or contracts as a continuing source of funds.**

A substantial portion of our revenues to date, albeit decreasing in 2007 and 2008, has been derived from federal government grants and research contracts. During the years ended December 31, 2006, 2007 and 2008, we generated revenues from awards made to us by the NIH between 2003 and 2008, to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them due to their own budgetary constraints. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing grants or contracts may be less than those received to date. Therefore, we will need to provide funding on our own or obtain other funding.

**If health care reform measures are enacted, our operating results and our ability to commercialize products could be adversely affected.**

In recent years, there have been numerous proposals to change the health care system in the U.S. and in foreign jurisdictions. Some of these proposals have included measures that would change the nature of and regulatory requirements relating to drug discovery, clinical testing and regulatory approvals, limit or eliminate payments for medical procedures and treatments, or subject the pricing of pharmaceuticals to government control. In some foreign countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In addition, as a result of the trend towards managed health care in the U.S., as well as legislative proposals to reduce government insurance programs, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved health care products.

If we or any of our collaborators succeed in bringing one or more of our products to market, third party payors may establish and maintain price levels insufficient for us to realize an appropriate return on our investment in product development. Significant changes in the health care system in the U.S. or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our operating results and our ability to raise capital and commercialize products.

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

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected.

Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all. We have obtained product liability insurance in the amount of \$10.0 million per occurrence, subject to a deductible and a \$10.0 million annual aggregate limitation. Where local statutory requirements exceed the limits of our existing insurance or where local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. Our present insurance coverage may not be adequate to cover claims brought against us. Some of our license and other agreements require us to obtain product liability insurance. Adequate insurance coverage may not be available to us at a reasonable cost in the future.

**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.

**Our stock price has a history of volatility. You should consider an investment in our stock as risky and invest only if you can withstand a significant loss.**

Our stock price has a history of significant volatility. Between January 1, 2006 and December 31, 2008, our stock price has ranged from \$30.83 to \$4.33 per share. Between January 1, 2009 and March 6, 2009, it has ranged from \$5.53 to \$10.81 per share. Historically, our stock price has fluctuated through an even greater range. At times, our stock price has been volatile even in the absence of significant news or developments relating to us. The stock prices of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years, and current financial and market conditions have resulted in widespread pressures on securities of issuers throughout the world economy. 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 involving our products or those of our competitors;
- changes in the status of any of our drug development programs, including delays in clinical trials or program terminations;
- developments regarding our efforts to achieve marketing approval for our products;
- developments in our relationships with Wyeth and Ono regarding the development and commercialization of RELISTOR;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
- developments in our relationships with other collaborative partners;
- developments in patent or other proprietary rights;
- governmental regulation;
- changes in reimbursement policies or health care legislation;
- public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
- our ability to fund on-going operations;
- fluctuations in our operating results; and
- general market conditions.

Purchases of our common shares pursuant to our April 24, 2008 announcement of our \$15.0 million share repurchase program may, depending on their timing, volume and form, result in our stock price to be higher than it would be in the absence of such purchases. If purchases under the program are not initiated or are discontinued, our stock price may fall.

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

At December 31, 2008, our directors and executive officers and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately one-fifth of our outstanding shares of common stock. At that date, our five largest stockholders, excluding our directors and executive officers and stockholders affiliated with Tudor, beneficially own or control in the aggregate approximately half of our outstanding shares. Our directors and executive officers and Tudor-related stockholders, should they choose to act together, could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could have the effect of delaying or preventing a change in control of us and, consequently, could adversely affect the market price of our common stock. Other significant but unrelated stockholders could also exert influence in such matters.

**Anti-takeover provisions may make the removal of our Board of Directors or management more difficult and discourage hostile bids for control of our company that may be beneficial to our stockholders.**

Our Board of Directors 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 certain of our 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 of Progenics or the removal of our Board of Directors or management more difficult;
- discourage hostile bids for control of Progenics in which stockholders may receive a premium for their shares of common stock; and
- otherwise dilute the rights of holders of our common stock and depress the market price of our common stock.

**If there are substantial sales of our common stock, the market price of our common stock could decline.**

Sales of substantial numbers of shares of common stock 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. In addition, some of our other stockholders are entitled to require us to register their shares of common stock for offer or sale to the public, and we have filed Form S-8 registration statements registering shares issuable pursuant to our equity compensation plans. Any sales by existing stockholders or holders of options may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common stock.

**Item 1B. Unresolved Staff Comments**

There were no unresolved SEC staff comments regarding our periodic or current reports under the Exchange Act as of December 31, 2008.

**Item 2. Properties**

As of December 31, 2008, we occupy in total approximately 145,900 square feet of laboratory, manufacturing and office space on a single campus in Tarrytown, New York, as follows:

<u>Leased Space</u>	<u>Area (Square Feet)</u>	<u>Termination Date</u>	<u>Other Terms</u>
Sublease 1	91,700	December 30, 2009	
Lease 1	32,600	December 31, 2009	Renewable for two five-year terms
Sublease 2	5,900	June 29, 2012	Four months rent-free beginning April 1, 2006; converts to Lease 2
Lease 2		December 31, 2014	
Lease 3	9,200	June 29, 2012	Three months rent-free beginning August 13, 2007; renewable for two five-year terms; lease incentive of \$276,300 provided by landlord
Lease 4	6,500	August 31, 2012	Renewable for two terms co-terminous with Lease 1
Total	<u>145,900</u>		

In addition to rents due under these agreements, 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.

**Item 4. Submission of Matters to a Vote of Security Holders**

No matters were submitted to a vote of stockholders during the fourth quarter of 2008.

## PART II

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

#### Price Range of Common Stock

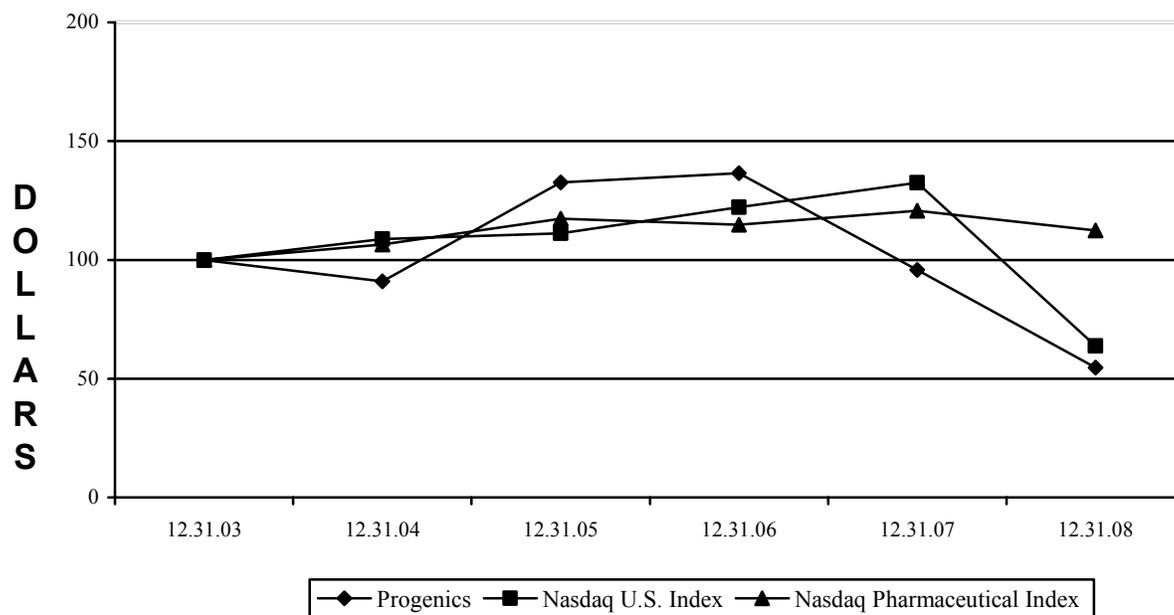
Our common stock is quoted on The NASDAQ Stock Market LLC under the symbol “PGNX.” The following table sets forth, for the periods indicated, the high and low sales price per share of the common stock, as reported on The NASDAQ Stock Market LLC. Such prices reflect inter-dealer prices, without retail mark-up, markdown or commission and may not represent actual transactions.

	High	Low
<b>Year ended December 31, 2007</b>		
First quarter	\$ 30.31	\$ 22.02
Second quarter	27.59	21.14
Third quarter	26.10	20.55
Fourth quarter	23.98	17.77
<b>Year ended December 31, 2008</b>		
First quarter	19.25	4.33
Second quarter	17.94	6.66
Third quarter	17.50	11.88
Fourth quarter	14.10	6.77

On March 6, 2009, the last sale price for our common stock, as reported by The NASDAQ Stock Market LLC, was \$5.75. There were approximately 354 holders of record of our common stock as of March 6, 2009.

#### Comparative Stock Performance Graph

The graph below compares 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 the investment in each equaled \$100 on December 31, 2003.



#### Dividends

We have not paid any dividends since our inception and currently anticipate that all earnings, if any, will be retained for development of our business and that no dividends on our common stock will be declared in the foreseeable future.

## **Share Repurchase Program**

During 2008, we repurchased 200,000 of our outstanding common shares; we did not repurchase any during the fourth quarter (see *Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview*).

## Item 6. Selected Financial Data

The selected financial data presented below as of December 31, 2007 and 2008 and for each of the three years in the period ended December 31, 2008 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, 2004, 2005 and 2006 and for each of the two years in the period ended December 31, 2005 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,				
	2004	2005	2006	2007	2008
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
Research and development from collaborator	\$ -	\$ -	\$58,415	\$65,455	\$59,885
Royalty income	-	-	-	-	146
Research and development from joint venture	2,008	988	-	-	-
Research grants and contracts	7,483	8,432	11,418	10,075	7,460
Other revenues	85	66	73	116	180
Total revenues	<u>9,576</u>	<u>9,486</u>	<u>69,906</u>	<u>75,646</u>	<u>67,671</u>
Expenses:					
Research and development	35,673	43,419	61,711	95,234	82,305
In-process research and development	-	-	13,209	-	-
License fees – research and development	390	20,418	390	942	2,830
General and administrative	12,580	13,565	22,259	27,901	28,834
Loss in joint venture	2,134	1,863	121	-	-
Depreciation and amortization	1,566	1,748	1,535	3,027	4,609
Total expenses	<u>52,343</u>	<u>81,013</u>	<u>99,225</u>	<u>127,104</u>	<u>118,578</u>
Operating loss	<u>(42,767)</u>	<u>(71,527)</u>	<u>(29,319)</u>	<u>(51,458)</u>	<u>(50,907)</u>
Other income (expense):					
Interest income	780	2,299	7,701	7,770	6,235
Interest expense	-	-	-	-	-
Loss on sale of marketable securities	(31)	-	-	-	-
Total other income	<u>749</u>	<u>2,299</u>	<u>7,701</u>	<u>7,770</u>	<u>6,235</u>
Net loss before income taxes	<u>(42,018)</u>	<u>(69,228)</u>	<u>(21,618)</u>	<u>(43,688)</u>	<u>(44,672)</u>
Income taxes	-	(201)	-	-	-
Net loss	<u>\$(42,018)</u>	<u>\$(69,429)</u>	<u>\$(21,618)</u>	<u>\$(43,688)</u>	<u>\$(44,672)</u>
Per share amounts on net loss:					
Basic and diluted	<u>\$(2.48)</u>	<u>\$(3.33)</u>	<u>\$(0.84)</u>	<u>\$(1.60)</u>	<u>\$(1.51)</u>

	December 31,				
	2004	2005	2006	2007	2008
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$31,207	\$173,090	\$149,100	\$170,370	\$141,374
Working capital	25,667	137,101	91,827	102,979	85,983
Total assets	39,545	184,003	165,911	189,539	157,833
Deferred revenue, long-term	-	-	16,101	9,131	-
Other liabilities, long-term	42	49	123	359	266
Total stockholders' equity	31,838	112,732	110,846	147,499	119,369

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

### Overview

**General.** We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward supportive care, virology and oncology. We commenced principal operations in 1988, became publicly traded in 1997 and throughout have been engaged primarily in research and development efforts, developing manufacturing capabilities, establishing corporate collaborations and raising capital. We have only recently begun to derive revenue from a commercial product. In order to commercialize the principal products that we have under development, we have been and continue to address a number of technological and clinical challenges and comply with comprehensive U.S. and non-U.S. regulatory requirements. We expect to incur additional operating losses in the future, which could increase significantly as we expand our clinical trial programs and other product development efforts.

Our sources of revenues through December 31, 2008 have been payments under our current and former collaboration agreements, from PSMA LLC, from research grants and contracts from the NIH related to our cancer and virology programs, from interest income and royalties. Beginning in January 2006, we have been recognizing revenues from Wyeth for reimbursement of our development expenses for RELISTOR as incurred, for the \$60.0 million upfront payment we received from Wyeth over the period of our development obligations and for any milestones or contingent events that are achieved during our collaboration with Wyeth. We have not recognized revenue from PSMA LLC for the years ended December 31, 2006, 2007 or 2008, since during 2006, prior to our acquisition of our former partner's membership interest in PSMA LLC on April 20, 2006, the partners had not approved a work plan and budget for 2006 and subsequently PSMA LLC has become our wholly owned subsidiary. To date, our product sales have consisted solely of limited revenues from the sale of research reagents. We expect that sales of research reagents in the future will not significantly increase over current levels.

A majority of our expenditures to date have been for research and development activities. During 2008, expenses for our HIV research program have increased significantly over those in 2006 and 2007 while expenses for our RELISTOR and cancer research programs declined compared to 2006 and 2007. We expect our expenses for RELISTOR will decline in 2009 and thereafter, which will result in less reimbursement revenues from Wyeth. We expect to incur significant development expenses for our other programs as these programs progress. A portion of these expenses is reimbursed through government funding.

At December 31, 2008, we had cash, cash equivalents and marketable securities totaling \$141.4 million. We expect that cash, cash equivalents and marketable securities on hand at December 31, 2008 will be sufficient to fund operations at current levels beyond one year. Cash used in operating activities for the year ended December 31, 2008 was \$28.3 million. We have had recurring losses and had, at December 31, 2008, an accumulated deficit of \$298.7 million. During the year ended December 31, 2008, we had a net loss of \$44.7 million. Our most recent public offering of common stock occurred during the year ended December 31, 2007, and we received net proceeds of \$57.1 million. Other than potential revenues from RELISTOR, which we expect to decline, we do not anticipate generating significant recurring revenues, from royalties, product sales or otherwise, in the near term, and we expect to incur significant expenses. Consequently, we may require significant additional external funding to continue our operations at their current levels in the future. Such funding may be derived from additional collaboration or licensing agreements with pharmaceutical or other companies or from the sale of our common stock or other securities to investors or government funding, but may also not be available to us on acceptable terms or at all.

**Supportive Care.** Our first commercial product, RELISTOR<sup>®</sup>, was approved by the FDA for sale in the United States in April 2008. Our collaboration partner, Wyeth Pharmaceuticals, commenced sales of RELISTOR subcutaneous injection in June, and we have begun earning royalties on world-wide sales. Regulatory approvals have also been obtained in Canada, the European Union, Australia and Venezuela, and marketing applications have been approved or are pending or scheduled in other countries. In October, we out-licensed to Ono Pharmaceutical Co., Ltd., Osaka, Japan, the rights to subcutaneous RELISTOR in Japan. We continue development and clinical trials with respect to other indications for RELISTOR.

In January 2009, Wyeth and Pfizer Inc. announced a definitive agreement under which Pfizer is to acquire Wyeth. We understand that the transaction is currently expected to close in late 2009 and is subject to a variety of conditions. The proposed acquisition of Wyeth by Pfizer does not trigger any change-of-control provisions in our collaboration with Wyeth, and we believe that if the acquisition occurs, the combined Pfizer/Wyeth organization will continue to have the same rights and responsibilities under the Collaboration following the acquisition as Wyeth had before. We cannot, however, predict how a combined Pfizer and Wyeth may view the utility and attractiveness of our Collaboration. As a result of completion of this proposed acquisition or for other reasons, Wyeth or Pfizer may change its strategic focus or pursue alternative technologies in a manner that results in reduced or delayed revenues to us. We cannot predict whether a combined Pfizer and Wyeth will determine to continue, seek to change or terminate our

Collaboration, or devote the same resources Wyeth currently dedicates to it. If a combined Wyeth and Pfizer were to terminate the Collaboration, we would no longer receive milestone and royalty payments and would need to undertake development and commercialization of RELISTOR ourselves or through another collaboration or licensing arrangement. We may not learn of their plans for RELISTOR and our Collaboration unless and until the proposed transaction closes.

In 2008, we earned \$25.0 million in milestone payments from Wyeth for FDA and European approvals of subcutaneous RELISTOR for the advanced illness setting, and in the second quarter of 2008 began earning royalties on Wyeth's sales of that product. In April 2008, our Board of Directors approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, funding for which came from the \$15.0 million milestone payment we received from Wyeth related to U.S. marketing approval for RELISTOR. Purchases under the program were to be made at our discretion subject to market conditions in the open-market or otherwise, and in accordance with the regulations of the SEC, including Rule 10b-18. During 2008, we repurchased 200,000 of our outstanding common shares. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have \$12.3 million remaining available for purchases under the program.

We and Wyeth are also developing subcutaneous RELISTOR for treatment of OIC outside the advanced illness setting, in individuals with chronic pain not related to cancer, such as severe back pain that requires treatment with opioids (a phase 3 trial conducted by Wyeth), and in individuals rehabilitating from an orthopedic surgical procedure in whom opioids are used to control post-operative pain (a hypothesis generating phase 2 trial conducted by us). We are no longer enrolling patients in this latter trial and are analyzing data from the treated population. Based on positive results from the one-month blinded portion of the phase 3 chronic pain study, we and Wyeth recently initiated and FDA-required one-year, open-label safety study in chronic, non-cancer pain patients which is intended to yield a consolidated safety database to enable filing an sNDA, which is now planned for submission by the end of 2010 for treatment of OIC in the chronic, non-cancer pain population.

We and Wyeth also have had in development an intravenous formulation of RELISTOR for the management of POI, a temporary impairment of the gastrointestinal tract function. Results from two phase 3 clinical trials of this formulation showed that treatment did not achieve primary or secondary end points. Recent results from a third phase 3 trial evaluating an intravenous formulation of RELISTOR in patients following abdominal hernia repair have confirmed these earlier findings.

Wyeth is leading development of an oral formulation of RELISTOR for the treatment of OIC in patients with chronic, non-cancer pain. We and Wyeth are evaluating information from optimization studies of a formulation of this product candidate to determine the next stages of development.

Development and commercialization of RELISTOR is being conducted under the Wyeth Collaboration Agreement. Under that agreement, we (i) have received an upfront payment from Wyeth, (ii) have received and are entitled to receive further additional payments as certain developmental milestones for RELISTOR are achieved, (iii) have been and are entitled to be reimbursed by Wyeth for expenses we incur in connection with the development of RELISTOR under an agreed-upon development plan and budget, and (iv) have received and are entitled to receive royalties and commercialization milestone payments. These payments will depend on continued success in development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth and the FDA and other regulatory bodies, as well as the outcome of clinical and other testing of RELISTOR. Many of these matters are outside our control. Manufacturing and commercialization expenses for RELISTOR are funded by Wyeth. Wyeth has elected, as it was entitled to do under the Collaboration Agreement, not to develop RELISTOR in Japan, and as provided in that Collaboration Agreement returned to us the rights to RELISTOR in Japan. As discussed below, we have out-licensed the rights to subcutaneous RELISTOR in Japan which we reacquired from Wyeth as a result of its election.

At inception of the Wyeth collaboration, Wyeth paid to us a \$60.0 million non-refundable upfront payment. Wyeth has made \$39.0 million in milestone payments since that time and is obligated to make up to \$295.0 million in additional payments to us upon the achievement of milestones and contingent events in the development and commercialization of RELISTOR, taking into account the Ono transaction discussed below. Costs for the development of RELISTOR incurred by Wyeth or us starting January 1, 2006 are paid by Wyeth. We are being reimbursed for our out-of-pocket development costs by Wyeth and receive reimbursement for our efforts based on the number of our full-time equivalent employees devoted to the development project, all subject to Wyeth's audit rights and possible reconciliation as provided in the Agreement. During the applicable royalty periods, Wyeth is obligated to pay to us royalties on the net sales of RELISTOR by Wyeth throughout the world other than Japan, where we have licensed the rights to subcutaneous RELISTOR to Ono.

In January 2006, we began recognizing revenue from Wyeth for reimbursement of our development expenses for RELISTOR as incurred during each quarter under the development plan agreed to by us and Wyeth. We also began recognizing revenue for a portion of the \$60.0 million upfront payment we received from Wyeth, based on the proportion of the expected total effort for us to complete our development obligations, as reflected in the most recent development plan and budget approved by us and Wyeth, that was actually performed during that quarter. Starting June 2008, we began recognizing royalty income based on the net sales of RELISTOR, as defined, by Wyeth.

In October 2008, we entered into an exclusive License Agreement with Ono under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan. Under that agreement, in November 2008 we received from Ono an upfront payment of \$15.0 million, and are entitled to receive potential development milestones of up to \$20.0 million, commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. These payments will depend on continued success in development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth, Ono, the FDA, Japanese pharmaceutical regulatory authorities and other regulatory bodies, as well as the outcome of clinical and other testing of RELISTOR. Many of these matters are outside our control. Ono also 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. Supervision of and consultation with respect to Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them.

As a result of the return of the Japanese rights, we will not receive from Wyeth, milestone payments related to the development of RELISTOR formulations in Japan. These potential future milestone payments would have totaled \$22.5 million (of which \$7.5 million related to the subcutaneous formulation of RELISTOR and the remainder to the intravenous and oral formulations). Taking these adjustments into account, we now have the potential to receive a total of \$334.0 million in development and commercialization milestone payments from Wyeth under the Wyeth Collaboration (of which \$60.0 million relate to the intravenous formulation of RELISTOR), and of which \$39.0 million (\$5.0 million relating to the intravenous formulation) have been paid to date.

**Virology.** In the area of virology, we are developing two viral-entry inhibitors: a humanized monoclonal antibody, PRO 140, for treatment of HIV, the virus that causes AIDS, and a proprietary orally-available small-molecule drug candidate, designated PRO 206, for treatment of HCV infection. We have recently selected for further clinical development the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for convenient, weekly self-administration, and we are conducting preclinical development activities in preparation for filing an IND application for PRO 206. We are also engaged in research regarding a prophylactic vaccine against HIV infection.

**Oncology.** In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal ADC directed against 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 also developing therapeutic vaccines designed to stimulate an immune response to PSMA.

## Results of Operations (amounts in thousands)

### Revenues:

Our sources of revenue during the years ended December 31, 2008, 2007 and 2006, included our Collaboration with Wyeth, which was effective on January 1, 2006, our research grants and contract from the NIH and, to a small extent, our sale of research reagents. In June 2008, we began recognizing royalty income from net sales by Wyeth of subcutaneous RELISTOR.

Sources of Revenue	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
				Percent Change	
Research from collaborator	\$59,885	\$65,455	\$58,415	(9%)	12%
Royalty income	146	-	-	N/A	N/A
Research grants and contract	7,460	10,075	11,418	(26%)	(12%)
Other revenues	180	116	73	55%	59%
	\$67,671	\$75,646	\$69,906	(11%)	8%

### 2008 vs. 2007

**Research revenue from collaborator** relates to our Collaboration with Wyeth. From the inception of the Wyeth Collaboration through December 31, 2008 we recognized as revenue: (i) in October 2006, \$5,000 milestone payment in connection with the initiation of the first phase 3 clinical trial of intravenous RELISTOR, (ii) in May 2007, \$9,000, representing two milestone payments, related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of RELISTOR in the U.S and European Union, (iii) in April 2008, \$15,000 milestone payment related to the FDA approval of subcutaneous RELISTOR and (iv) in July 2008, \$10,000 milestone payment related to the European approval of subcutaneous formulation of RELISTOR. We have analyzed the facts and circumstances of the five milestones achieved since inception of the

Wyeth Collaboration through December 31, 2008, and believe that they met those criteria for revenue recognition upon achievement of the respective milestones. See *Critical Accounting Policies – Revenue Recognition*.

During the years ended December 31, 2008 and 2007, we recognized \$59,885 and \$65,455, respectively, of revenue from Wyeth, consisting of (i) \$10,228 and \$16,378, respectively, of the \$60,000 upfront payment we received upon entering into our Collaboration in December 2005, (ii) \$24,657 and \$40,077, respectively, as reimbursement of our development expenses, and (iii) \$25,000 and \$9,000, respectively, of non-refundable payments earned upon the achievement of milestones defined in the Wyeth Collaboration.

From the inception of the Wyeth Collaboration through December 31, 2008, we recognized \$45,437 of revenue from the \$60,000 upfront payment, \$99,318 as reimbursement for our development costs, and a total of \$39,000 for non-refundable milestone payments.

We recognize a portion of the upfront payment in a reporting period in accordance with the proportionate performance method, which is based on the percentage of actual effort performed on our development obligations in that period relative to total effort expected for all of our performance obligations under the arrangement, as reflected in the most recent development plan and budget approved by Wyeth and us. During the third quarter of 2007, a revised budget was approved, which extended our performance period to the end of 2009 and, thereby, decreased the amount of revenue we are recognizing in each reporting period. As a result, the amount of revenue recognized from the upfront payment during the year ended December 31, 2008 declined by \$6,150 as compared to 2007.

As of December 31, 2008, relative to the \$15.0 million upfront payment from Ono, we have recorded \$15.0 million as deferred revenue – current, which we expect to recognize as revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

**Royalty income.** We began earning royalties from net sales by Wyeth of subcutaneous RELISTOR in June 2008. During the year ended December 31, 2008, we earned royalties of \$665, based on the net sales of RELISTOR and we recognized \$146 of royalty income. As of December 31, 2008, we have recorded a cumulative total of \$519 as deferred revenue – current. The \$519 of deferred royalty revenue is expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR, which we currently estimate will be in 2009. Our royalties from net sales by Wyeth of RELISTOR, as defined, are based on royalty rates under our Collaboration. These rates can range up to 30% of U.S. and 25% of foreign net sales at the highest sales levels. Royalty rates will increase on incremental sales as net sales in a calendar year exceed specified levels.

**Research grants and contract.** In 2003, we were awarded a contract (NIH Contract) by the NIH to develop a prophylactic vaccine (ProVax) designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. Funding under the NIH Contract provides for pre-clinical research, development and early clinical testing. These funds are being used principally in connection with our ProVax HIV vaccine program. The NIH Contract originally provided for up to \$28,562 in funding to us, subject to annual funding approvals and compliance with its terms, over five years. The total of our approved award under the NIH Contract through December 2008 amounted to \$15,509. Funding under this contract includes the payment of an aggregate of \$1,617 in fees, subject to achievement of specified milestones. Through December 31, 2008, we had recognized revenue of \$15,509 from this contract, including \$180 for the achievement of two milestones. We were informed by the NIH that it has decided to fund the NIH Contract only through December 2008. We have applied for continued funding for this program and are funding it with our own resources pending a decision on that application.

Revenues from research grants and contract from the NIH decreased to \$7,460 for the year ended December 31, 2008 from \$10,075 for the year ended December 31, 2007; \$5,251 and \$6,185 from grants and \$2,209 and \$3,890 from the NIH Contract for the years ended December 31, 2008 and 2007, respectively. The decrease in grant and contract revenue resulted from fewer reimbursable expenses in 2008 than in 2007 on new and continuing grant related projects, and decreased activity under the NIH Contract.

**Other revenues,** primarily from increased orders for research reagents, increased to \$180 for the year ended December 31, 2008 from \$116 for the year ended December 31, 2007.

#### **2007 vs. 2006**

**Research revenues from collaborator.** During the years ended December 31, 2007 and 2006, we recognized \$65,455 and \$58,415, respectively, of revenue from Wyeth, consisting of (i) \$16,378 and \$18,831, respectively, of the \$60,000 upfront payment we received upon entering into our Collaboration in December 2005, (ii) \$40,077 and \$34,584, respectively, as reimbursement of our development expenses, and (iii) \$9,000 and \$5,000, respectively, of non-refundable payments earned upon the achievement of milestones defined in the Wyeth Collaboration Agreement.

**Research grants and contract.** Revenues from research grants and contract from the NIH decreased to \$10,075 for the year ended December 31, 2007 from \$11,418 for the year ended December 31, 2006; \$6,185 and \$8,052 from grants and \$3,890 and \$3,366 from the NIH Contract for the years ended December 31, 2007 and 2006, respectively. The decrease in grant revenue resulted from completion of certain grants in 2006 and fewer reimbursable expenses in 2007 than in 2006 on new and continuing grant related projects. In addition, there was increased activity under the NIH Contract.

**Other revenues,** primarily from higher orders for research reagents increased to \$116 for the year ended December 31, 2007 from \$73 for the year ended December 31, 2006. We received more orders for research reagents during 2007.

**Expenses:**

**Research and Development Expenses** include scientific labor, supplies, facility costs, clinical trial costs, product manufacturing costs, royalty payments and license fees. Research and development expenses, including in-process research and development, license fees and royalty expense, decreased to \$85,135 for the year ended December 31, 2008 from \$96,176 for the year ended December 31, 2007, and increased from \$75,310 in the year ended December 31, 2006. Research and development expenses for 2006 include a one-time charge of \$13,209 related to our purchase of a former member's equity interest in PSMA LLC (see *Business – Oncology – PSMA*). During 2008, the decrease in research and development expenses over those in 2007 and 2006, net of the one-time charges in 2006, was primarily due to a decrease in activity related to the PSMA clinical program, and, to a lesser extent, net activity related to our HCV research and pre-clinical programs, partially offset by an increase in the PRO 140 program. Expenses for RELISTOR in 2008 were also lower than in 2007 and 2006, due to enrollment delays in the phase 2 trial for subcutaneous RELISTOR and conclusion of the phase 3 trial for intravenous RELISTOR. See *Liquidity and Capital Resources – Uses of Cash*, for details of the changes in these expenses by project. Beginning in 2006, Wyeth is reimbursing us for development expenses we incur related to RELISTOR under the development plan agreed to between Wyeth and us. A portion of our expenses related to our HIV, HCV and PSMA programs is funded through grants and a contract from the NIH (see *Revenues- Research Grants and Contract*). The changes in research and development expense, by category of expense, are as follows:

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Salaries and benefits (cash)</b>	<b>\$24,383</b>	<b>\$24,061</b>	<b>\$17,013</b>	<b>1%</b>	<b>41%</b>

*2008 vs. 2007* Company-wide compensation increased due to an increase in average headcount to 196 from 190 for the years ended December 31, 2008 and 2007, respectively, in the research and development, manufacturing and clinical departments.

*2007 vs. 2006* Company-wide compensation increased due to an increase in average headcount to 190 from 134 for the years ended December 31, 2007 and 2006, respectively, in the research and development, manufacturing and clinical departments.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Share-based compensation (non-cash)</b>	<b>\$7,241</b>	<b>\$7,104</b>	<b>\$5,814</b>	<b>2%</b>	<b>22%</b>

*2008 vs. 2007* Increase due to increase in average headcount, increase in employee stock purchase plan expenses and additional grants made during the year ended December 31, 2008, partially offset by lower compensation expense due to fully vested awards and an increase in the directors and officers forfeiture rate.

*2007 vs. 2006* Increase due to increase in headcount and changes in the fair value of our common stock.

See *Critical Accounting Policies – Share-Based Payment Arrangements*.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Clinical trial costs</b>	<b>\$14,127</b>	<b>\$19,225</b>	<b>\$9,485</b>	<b>(27%)</b>	<b>103%</b>

*2008 vs. 2007* Decrease primarily related to RELISTOR (\$6,686), due to reduced clinical trial activities in 2008 and remaining costs for termination of GMK study in 2007 (\$1,534). These decreases were partially offset by an increase in HIV (\$3,122) due to increased PRO 140 clinical trial activities in 2008.

*2007 vs. 2006* Increase primarily related to RELISTOR (\$10,901) due to the global pivotal phase 3 clinical trial of the intravenous formulation of RELISTOR which began in the fourth quarter of 2006 and Other projects (\$2). The increases were partially offset by

decreases in Cancer (\$778), due to termination of the GMK study in the second quarter of 2007, and HIV-related costs (\$385), resulting from a decline in clinical site payments and other clinical expenses related to the phase 1b clinical trial of PRO 140 for which enrollment and dosing of subjects was complete by December 2006. During 2007, data from that trial was analyzed.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Laboratory supplies</b>	<b>\$3,944</b>	<b>\$5,196</b>	<b>\$5,522</b>	<b>(24%)</b>	<b>(6%)</b>

*2008 vs. 2007* Decrease in HIV (\$808), due to purchase of less drug supplies in 2008 compared to 2007, Cancer (\$235), due to fewer expenses for PSMA and GMK and Other projects (\$209).

*2007 vs. 2006* Increase in HIV-related costs (\$1,134), due to internal manufacture of drug materials for the phase 2 PRO 140 clinical trial, and in Other projects (\$615), primarily Hepatitis C virus research costs. The increases were partially offset by a decrease in RELISTOR (\$1,564) due to the purchase of more RELISTOR drug in the 2006 period than in the 2007 period, and Cancer (\$511) due to a decrease in basic research costs in 2007 for Cancer (primarily PSMA).

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Contract manufacturing and subcontractors</b>	<b>\$21,681</b>	<b>\$26,051</b>	<b>\$12,448</b>	<b>(17%)</b>	<b>109%</b>

*2008 vs. 2007* Decrease in Cancer (\$5,401), primarily due to contract manufacturing expenses for PSMA in 2007 but not in 2008, and RELISTOR (\$2,301), partially offset by increases in HIV (\$3,052) due to manufacturing expenses for PRO 140 in 2008 but not in 2007 and Other (\$280). These expenses are related 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.

*2007 vs. 2006* Increase in HIV (\$8,228), Cancer (\$5,274) and Other projects (\$1,791), which was partially offset by a decrease in RELISTOR (\$1,690) related to clinical trials under our Collaboration with Wyeth. These expenses are related 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.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Consultants</b>	<b>\$3,514</b>	<b>\$4,722</b>	<b>\$5,286</b>	<b>(26%)</b>	<b>(11%)</b>

*2008 vs. 2007* Decrease in RELISTOR (\$1,579) and Other projects (\$174), partially offset by increases in HIV (\$294) and Cancer (\$251). These expenses are related to the monitoring of clinical trials as well as the analysis of data from completed clinical trials and vary as the timing and level of such services are required.

*2007 vs. 2006* Decrease in RELISTOR (\$1,351) partially offset by increases in HIV (\$350), Cancer (\$107) and Other projects (\$330). These expenses are related to the monitoring of clinical trials as well as the analysis of data from completed clinical trials and vary as the timing and level of such services are required.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>License fees</b>	<b>\$2,830</b>	<b>\$942</b>	<b>\$390</b>	<b>200%</b>	<b>142%</b>

*2008 vs. 2007* Increase primarily due to HIV (\$1,100), RELISTOR (\$522) and Cancer (\$266) expenses in 2008 but not in 2007.

*2007 vs. 2006* Increase primarily related to our HIV program (\$30), Cancer (\$412) related to PSMA license agreements and RELISTOR (\$110), related to payments to the University of Chicago.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Royalty expense</b>	<b>\$15</b>	<b>\$-</b>	<b>\$-</b>	<b>N/A</b>	<b>N/A</b>

We incurred \$67 of royalty costs and recognized \$15 of royalty expenses during the year ended December 31, 2008. As of December 31, 2008, we recorded a cumulative total of \$52 of deferred royalty costs from the royalty costs incurred in the last three quarters of 2008. The \$52 of deferred royalty costs are expected to be recognized as royalty expense over the period of our development

obligations relating to RELISTOR.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Other operating expenses</b>	<b>\$7,400</b>	<b>\$8,875</b>	<b>\$19,352</b>	<b>(17%)</b>	<b>(54%)</b>

*2008 vs. 2007* Decrease primarily in computer expenses (\$1,760), insurance (\$294), facilities (\$186) and travel (\$102), partially offset by an increase in other operating expenses (\$21) and rent (\$846).

*2007 vs. 2006* Decrease primarily due to expenses in 2006 related to our purchase of a former member's equity interest in PSMA LLC, which are included in in-process research and development (\$13,209) and travel (\$21), partially offset by an increase in rent (\$579), facilities costs (\$202), insurance costs (\$128), other operating expenses (\$172) and increased computer software costs in 2007 (\$1,672), related to the preparation for submission of a NDA in March 2007.

**General and Administrative Expenses** increased to \$28,834 in the year ended December 31, 2008 from \$27,901 in the year ended December 31, 2007 and from \$22,259 in the year ended December 31, 2006, as follows:

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Salaries and benefits (cash)</b>	<b>\$8,610</b>	<b>\$7,243</b>	<b>\$5,942</b>	<b>19%</b>	<b>22%</b>

*2008 vs. 2007* Increase due to compensation increases and an increase in average headcount to 52 from 43 in the general and administrative departments for the years ended December 31, 2008 and 2007, respectively.

*2007 vs. 2006* Increase due to compensation increases and an increase in average headcount to 43 from 32 in the general and administrative departments for the years ended December 31, 2007 and 2006, respectively, including the hiring of our Vice President, Commercial Development and Operations in January 2007.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Share-based compensation (non-cash)</b>	<b>\$6,892</b>	<b>\$8,202</b>	<b>\$6,840</b>	<b>(16%)</b>	<b>20%</b>

*2008 vs. 2007* Decrease due to compensation awards becoming fully vested and an increase in directors and officers forfeiture rate, partially offset by greater employee stock purchase plan expenses and issuance of new grants.

*2007 vs. 2006* Increase due to increase in headcount and changes in the fair value of our common stock.

See *Critical Accounting Policies – Share-Based Payment Arrangements*.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Consulting and professional fees</b>	<b>\$7,838</b>	<b>\$6,481</b>	<b>\$4,891</b>	<b>21%</b>	<b>33%</b>

*2008 vs. 2007* Increase due primarily to increases in consultants (\$1,135), legal and patent fees (\$132) and other miscellaneous costs (\$158), which were partially offset by a decrease in audit and tax fees (\$68).

*2007 vs. 2006* Increase due primarily to increases in consultants (\$632), legal and patent fees (\$1,138) and other miscellaneous costs (\$15), which were partially offset by a decrease in audit and tax fees (\$195).

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Other operating expenses</b>	<b>\$5,494</b>	<b>\$5,975</b>	<b>\$4,586</b>	<b>(8)%</b>	<b>30%</b>

*2008 vs. 2007* Decrease in recruiting (\$452), facilities (\$142), investor relations (\$74), taxes (\$27) and other operating expenses (\$55), partially offset by increases in rent (\$269).

*2007 vs. 2006* Increase in computer supplies and software (\$219), rent (\$184), recruiting (\$125), travel (\$69), utilities and facilities costs (\$466), investor relations (\$176) and other operating expenses (\$290), partially offset by decreases in insurance (\$101) and corporate sales and franchise taxes (\$39).

**Loss in Joint Venture:**

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Loss in Joint Venture</b>	\$-	\$-	\$121	N/A	(100%)

*2007 vs. 2006* Loss in joint venture decreased to \$0 for the year ended December 31, 2007 from \$121 for the year ended December 31, 2006. On April 20, 2006, PSMA LLC became our wholly owned subsidiary and, accordingly, we did not recognize loss in joint venture from the date of acquisition.

**Depreciation and Amortization:**

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Depreciation and amortization</b>	\$4,609	\$3,027	\$1,535	52%	97%

*2008 vs. 2007* Depreciation expense increased to \$4,609 for the year ended December 31, 2008 from \$3,027 for the year ended December 31, 2007, due to increased amortization of leasehold improvements. Approximately \$3.8 million of leasehold improvements was placed in service during 2007, which is being amortized through the end of the lease term of December 31, 2009.

*2007 vs. 2006* Depreciation expense increased to \$3,027 for the year ended December 31, 2007 from \$1,535 for the year ended December 31, 2006. We purchased capital assets and made leasehold improvements in both years to increase our research and manufacturing capacity. During 2007, \$5.8 million of machinery and equipment and leasehold improvements that had been included in construction in progress at December 31, 2006, representing about 28% of the December 31, 2006 balance of fixed assets, were placed in operation and depreciated.

**Other Income:**

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008 vs. 2007</u>	<u>2007 vs. 2006</u>
	Percent change				
<b>Other income</b>	\$6,235	\$7,770	\$7,701	(20)%	1%

*2008 vs. 2007* Interest income decreased to \$6,235 for the year ended December 31, 2008 from \$7,770 for the year ended December 31, 2007. Interest income, as reported, is primarily the result of investment income from our marketable securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those marketable securities. For the years ended December 31, 2008 and 2007, investment income decreased to \$7,195 from \$7,325, respectively, due to a decrease in interest rates and lower average balance of cash equivalents and marketable securities in 2008 than in 2007. Amortization of premiums, net of discounts, was (\$960) and \$445 for the years ended December 31, 2008 and 2007, respectively.

*2007 vs. 2006* Interest income increased to \$7,770 for the year ended December 31, 2007 from \$7,701 for the year ended December 31, 2006. Interest income, as reported, is primarily the result of investment income from our marketable securities, decreased by the amortization of premiums we paid or increased by the amortization of discounts we received for those marketable securities. For the years ended December 31, 2007 and 2006, investment income decreased to \$7,325 from \$7,710, respectively, due to a lower average balance of cash equivalents and marketable securities in 2007 than in 2006. Amortization of premiums, net of discounts, was \$445 and \$9 for the years ended December 31, 2007 and 2006, respectively.

**Income Taxes:**

For the years ended December 31, 2008, 2007 and 2006, we had losses both for book and tax purposes.

**Net Loss:**

Our net loss was \$44,672 for the year ended December 31, 2008, \$43,688 for the year ended December 31, 2007 and \$21,618 for the year ended December 31, 2006.

## Liquidity and Capital Resources

We have to date generated only modest amounts of product and royalty revenue, and consequently have relied principally on external funding and our Collaboration with Wyeth to finance our operations. We have funded our operations since inception primarily through private placements of equity securities, payments received under collaboration agreements, public offerings of common stock, funding under government research grants and contracts, interest on investments, proceeds from the exercise of outstanding options and warrants and sale of our common stock under our two employee stock purchase plans (Purchase Plans). At December 31, 2008, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$141.4 million compared with \$170.4 million at December 31, 2007. We expect that our existing cash, cash equivalents and marketable securities at December 31, 2008 are sufficient to fund current operations beyond one year. Our cash flow from operating activities was negative for the years ended December 31, 2008, 2007 and 2006 due primarily to the excess of expenditures on our research and development programs and general and administrative costs related to those programs over cash received from collaborators and government grants and contracts to fund such programs, as described below.

### Sources of Cash

**Operating Activities.** Our Collaboration with Wyeth provided us with a \$60.0 million upfront payment in December 2005. In addition, since January 2006, Wyeth has been reimbursing us for development expenses we incur related to RELISTOR under the development plan agreed to between us, which is currently expected to continue through 2009. For the years ended December 31, 2008 and 2007, we received \$24.7 million and \$40.1 million, respectively, of such reimbursement. Since inception of the Wyeth Collaboration, Wyeth has made \$39.0 million in milestone payments to us upon the achievement of certain events. In May 2007, we earned \$9.0 million, representing two milestone payments, related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of RELISTOR for the treatment of OIC in patients receiving palliative care in the U.S. and the European Union. Approval of the U.S. application in April 2008 resulted in our earning a \$15.0 million milestone payment, which was recognized in the second quarter of 2008. In July 2008, we earned \$10.0 million milestone payment for the European approval of subcutaneous RELISTOR. Wyeth has also submitted applications for the marketing of RELISTOR in Canada and Australia, which were approved in March 2008 and November 2008, respectively. In October 2006, we earned a \$5.0 million milestone payment in connection with the start of a phase 3 clinical trial of intravenous RELISTOR for the treatment of POI. Wyeth is obligated to make up to \$295 million in additional payments to us upon the achievement of milestones and other contingent events in the development and commercialization of RELISTOR. Wyeth is also responsible for all commercialization activities related to RELISTOR products, other than that to be conducted by Ono. We are entitled to receive royalty payments from Wyeth as the product is sold in the various countries (other than Japan) where marketing approval has been obtained. We are also entitled to receive royalty payments upon the sale of all other products developed under the Wyeth Collaboration Agreement.

Under our License Agreement with Ono, we received from Ono an upfront payment of \$15.0 million, and are entitled to receive potential development milestone payments of up to \$20.0 million, commercial milestones and royalties on sales of subcutaneous RELISTOR in Japan. Ono is also responsible for development and commercialization costs for subcutaneous RELISTOR in Japan. As of December 31, 2008, relative to the \$15.0 million upfront payment from Ono, we have recorded \$15.0 million as deferred revenue – current, which we expect to recognize as revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

The funding by Wyeth and Ono of development costs for RELISTOR generally enhances our ability to devote current and future resources to other research and development programs. We may also enter into other collaboration agreements, license or sale transactions or royalty sales or financings with respect to our products and product candidates. We cannot forecast with any degree of certainty, however, which products or indications, if any, will be subject to future arrangements, or how they would affect our capital requirements. The consummation of other agreements would further allow us to advance other projects with current funds.

In 2003, we were awarded a contract by the NIH to develop a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. Funding under the NIH Contract provided for pre-clinical research, development and early clinical testing. These funds are being used principally in connection with our ProVax HIV vaccine program. The NIH Contract originally provided for up to \$28.6 million in funding to us, subject to annual funding approvals and compliance with its terms, over five years. The total of our approved award under the NIH Contract through December 2008 is \$15.5 million. Funding under this contract includes the payment of an aggregate of \$1.6 million in fees, subject to achievement of specified milestones. Through December 31, 2008, we had recognized revenue of \$15.5 million from this contract, including \$0.2 million for the achievement of two milestones. We were informed by the NIH that it has decided to fund this contract only through December 2008. We have applied for continued funding for this program and are funding it with our own resources pending a decision on that application.

A substantial portion of our revenues to date has been derived from federal government grants and research contracts. During

the years ended December 31, 2006, 2007 and 2008, we generated revenues from awards made to us by the NIH between 2003 and 2008, to partially fund some of our programs. For the years ended December 31, 2008, 2007 and 2006, we recognized \$5.3 million, \$6.2 million and \$8.1 million, respectively, of revenue from all of our NIH grants.

Changes in Accounts receivable and Accounts payable for the years ended December 31, 2008, 2007 and 2006 resulted from the timing of receipts from the NIH and Wyeth, and payments made to trade vendors in the normal course of business.

Other than amounts to be received from Wyeth, Ono and from currently approved grants, we have no committed 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.** We purchase and sell marketable securities in order to provide funding for operations. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available-for-sale.

A substantial portion of our cash and cash equivalents are guaranteed by the U.S. Treasury or Federal Deposit Insurance Corporation's guarantee programs. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available for sale and are predominantly not guaranteed. These investments, while rated investment grade by the Standard & Poor's and Moody's rating agencies and predominantly having scheduled maturities in the first three quarters of 2009, are heavily concentrated in the U.S. financial sector, which continues to be under extreme stress.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at December 31, 2008, we continue to hold approximately \$4.1 million of auction rate securities which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. To date, we have received all scheduled interest payments on these securities. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, the issuer calls or restructures the underlying security, the underlying security matures and is paid, or a buyer outside the auction process emerges.

We monitor markets for our investments, but cannot guarantee that additional losses will not be required to be recorded. 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. 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.

Our marketable securities are purchased and, in the case of auction rate securities, sold by third-party brokers in accordance with our investment policy guidelines. Our brokerage account requires that all marketable securities be held to maturity unless authorization is obtained from us to sell earlier. In fact, we have a history of holding all marketable securities to maturity. We, therefore, consider that we have the intent and ability to hold any securities with unrealized losses until a recovery of fair value (which may be maturity), and we do not consider these marketable securities to be other than temporarily impaired at December 31, 2008.

**Financing Activities.** During the years ended December 31, 2008, 2007 and 2006, we received cash of \$6.5 million, \$7.8 million and \$7.1 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants, from the sale of our common stock under our Purchase Plans and from sale of common stock in public offering in 2007. 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 Purchase Plans.

In 2007, we completed a public offering of 2.6 million shares of our common stock, pursuant to a shelf registration statement that had been filed with the SEC in 2006, which had registered 4.0 million shares of our common stock; that registration statement has now expired. We received proceeds of \$57.3 million, or \$22.04 per share, which was net of underwriting discounts and commissions of approximately \$2.9 million, and paid approximately \$0.2 million in other offering expenses.

In the past year, we obtained approvals from the FDA, as well as European Union, Canadian, Australian, Venezuelan and other regulatory authorities, for our first commercial product, RELISTOR. We continue development and clinical trials with respect to RELISTOR and our other product candidates. Unless we obtain regulatory approval from the FDA for additional product candidates and/or enter into agreements with corporate collaborators with respect to the development of our technologies in addition to that for RELISTOR, we will be required to fund our operations for periods in the future, by seeking additional financing through future

offerings of equity or debt securities or funding from additional 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 would seriously jeopardize the future success of our business.

## Uses of Cash

**Operating Activities.** The majority of our cash has been used to advance our research and development programs. We currently have major research and development programs investigating supportive care, virology and oncology, and are conducting several smaller research projects in the areas of virology and oncology. Our total expenses for research and development from inception through December 31, 2008 have been approximately \$478.5 million. For various reasons, many of which are outside of our control, including the early stage of certain of our programs, the timing and results of our clinical trials and our dependence in certain instances on third parties, we cannot estimate the total remaining costs to be incurred and timing to complete our research and development programs. Under our Collaboration with Wyeth, we are able to estimate that those remaining costs for the subcutaneous and intravenous formulations of RELISTOR, based upon the development plan and budget approved by us and Wyeth, which may be subject to further revision, are \$15.8 million, over the period from January 1, 2009 to December 31, 2009.

For the years ended December 31, 2008, 2007 and 2006, research and development costs incurred, by project, were as follows. Expenses for Cancer for 2006 include \$13.2 million related to our purchase of a former member's interest in the PSMA joint venture, (see *Business – Oncology – Prostate Cancer – PSMA*, above for more details):

	<b>For the Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
		(in millions)	
RELISTOR	\$ 25.4	\$ 41.5	\$ 32.1
HIV	39.4	29.0	15.8
Cancer	10.8	16.1	23.2
Other programs	9.5	9.6	4.2
Total	<u>\$ 85.1</u>	<u>\$ 96.2</u>	<u>\$ 75.3</u>

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. Manufacturing and commercialization expenses for RELISTOR are funded by Wyeth in the U.S. and outside the U.S. except for Japan, where development, manufacturing and commercialization expenses are required to be funded by Ono. However, if we exercise our option to co-promote RELISTOR products in the U.S., which must be approved by Wyeth, we will be required to establish and fund a sales force, which we currently do not have. If we commercialize any other product candidate other than with a collaborator, we would also require additional funding to establish manufacturing and marketing capabilities.

Our purchase of rights from our methylalntrexone licensors in December 2005 has extinguished our cash payments that would have been due to those licensors in the future upon the achievement of certain events, including sales of RELISTOR products. We continue, however, to be responsible to make payments (including royalties) to the University of Chicago upon the occurrence of certain events.

Costs incurred by PSMA LLC from January 1, 2006 to April 20, 2006 were funded from PSMA LLC's cash reserves. We are continuing to conduct the PSMA research and development projects on our own subsequent to our acquisition of PSMA LLC, on April 20, 2006, and are required to fund the entire amount of such efforts, thus, increasing our cash expenditures. We are funding PSMA-related research and development efforts from our internally-generated cash flows. We are also continuing to receive funding from the NIH for a portion of our PSMA-related research and development costs.

**Investing Activities.** During the years ended December 31, 2008, 2007 and 2006, we have spent \$2.2 million, \$5.2 million and \$8.8 million, respectively, on capital expenditures. Those expenditures have been related to the expansion of our office, laboratory and manufacturing facilities and the purchase of more laboratory equipment for our ongoing and future research and development projects, including the purchase of a second 150-liter bioreactor in February 2007 for the manufacture of research and clinical products.

## Contractual Obligations

Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of December 31, 2008 for future payments under these agreements:

	<b>Total</b>	<b>Payments due by December 31,</b>			
		<b>2009</b>	<b>2010-2011</b>	<b>2012-2013</b>	<b>Thereafter</b>
			(in millions)		
Operating leases	\$ 5.0	\$ 3.2	\$ 1.0	\$ 0.6	\$ 0.2
License and collaboration agreements (1)	82.5	2.1	4.8	12.7	62.9
Total	<u>\$ 87.5</u>	<u>\$ 5.3</u>	<u>\$ 5.8</u>	<u>\$ 13.3</u>	<u>\$ 63.1</u>

- (1) Assumes attainment of milestones covered under each agreement, including those by PSMA LLC. The timing of the achievement of the related milestones is highly uncertain, and accordingly the actual timing of payments, if any, is likely to vary, perhaps significantly, relative to the timing contemplated by this table.

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

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

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

## Off-Balance Sheet Arrangements and Guarantees

We have no 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 United States of America. Our significant accounting policies are disclosed in Note 2 to our financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2008. 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), Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21) "Accounting for Revenue Arrangements with Multiple Deliverables" and EITF Issue No. 99-19 (EITF 99-19) "Reporting Revenue Gross as a Principal Versus Net as an Agent." Our license and co-development agreement with Wyeth includes a non-refundable upfront license fee, reimbursement of development costs, research and development payments based upon our achievement of clinical development milestones, contingent payments based upon the achievement by Wyeth of defined events and royalties on product sales. We began recognizing research revenue from Wyeth on January 1, 2006. During the years ended December 31, 2008, 2007 and 2006, we also recognized revenue from government research grants and contract, which are used to subsidize a portion of certain of our research projects (Projects), exclusively from the NIH. We also recognized revenue from the sale of research reagents during those periods.

Non-refundable upfront license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and steering or other committee services, can be separated in accordance with EITF 00-21. We would recognize upfront license payments as revenue upon delivery of the license only if the license had standalone value and the fair value of the undelivered performance obligations, typically including research or steering or other committee services, could be determined. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value, or (ii) have standalone value but the fair value of any of the undelivered performance obligations could not be determined, the upfront license payments would be recognized as revenue over the estimated period of when our performance obligations are performed.

We must determine the period over which our performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents will typically be used as the measure of performance. Under the proportionate performance method, revenue related to upfront license payments is recognized in any period as the percent of actual effort expended in that period relative to total effort for all of our performance obligations under the arrangement. We are recognizing revenue related to the upfront license payment we received from Wyeth using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Wyeth Collaboration based upon the most current budget approved by both Wyeth and us. Such performance obligations are provided by us on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. Since we have no obligation to develop the subcutaneous and intravenous formulations of RELISTOR outside the U.S. or the oral formulation at all and have no significant commercialization obligations for any product, recognition of revenue for the upfront payment is not required during those periods, if they extend beyond the period of our development obligations.

During the course of a collaboration agreement, *e.g.*, the Wyeth Collaboration, that involves a development plan and budget, the amount of the upfront license payment that is recognized as revenue in any period will increase or decrease as the percentage of actual effort increases or decreases, as described above. When a new budget is approved, the remaining unrecognized amount of the upfront license fee will be recognized prospectively, using the methodology described above and applying any changes in the total estimated effort or period of development that is specified in the revised approved budget. The amounts of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 were based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amounts of revenue recognized in those periods. During the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased significantly based upon a revised development budget approved by both us and Wyeth. As a result, the period over which our obligations will extend, and over which the upfront payment will be amortized, was extended from the end of 2008 to the end of 2009. Consequently, the amount of revenue recognized from the upfront payment in the year ended December 31, 2008 declined relative to that in the comparable period of 2007. Due to the significant judgments involved in determining the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement, further changes in any of those judgments are reasonably likely to occur in the future which could have a material impact on our revenue recognition. If a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an upfront payment at the time of the termination.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement and the performance obligations are provided on a best-efforts basis, then the total upfront license payments would be recognized as

revenue on a straight-line basis over the period we expect to complete our performance obligations.

If we are involved in a steering or other committee as part of a multiple element 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. In relation to the Wyeth Collaboration, we have assessed the nature of our involvement with the JSC, JDC and JCC. Our involvement in the first two such committees is one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. We have combined the committee obligations with the other development obligations and are accounting for these obligations during the development phase as a single unit of accounting. After the development period, however, we have assessed the nature of our involvement with the committees to be a right, rather than an obligation. Our assessment is based upon the fact we negotiated to be on these committees as an accommodation for our granting of the license for RELISTOR to Wyeth. Further, Wyeth has been granted by us an exclusive license (even as to us) to the technology and know-how regarding RELISTOR and has been assigned the agreements for the manufacture of RELISTOR by third parties. Following regulatory approval of the subcutaneous and intravenous formulations of RELISTOR, Wyeth is required to continue to develop the oral formulation and to commercialize all formulations as provided in the Wyeth Collaboration, for which it is capable and responsible. During those periods, the activities of these committees will be focused on Wyeth's development and commercialization obligations. As discussed in *Overview – Supportive Care*, Wyeth returned the rights to RELISTOR with respect to Japan to us in connection with its election not to develop RELISTOR there and the transaction with Ono. As a result, Wyeth is now responsible for the development of the oral formulation worldwide excluding Japan and the intravenous and subcutaneous formulations outside the U.S., other than Japan.

Collaborations may also contain substantive milestone payments. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (i) the milestone payment is non-refundable, (ii) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (iii) substantive effort is involved in achieving the milestone, (iv) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (v) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment (Substantive Milestone Method). During October 2006, May 2007, April 2008 and July 2008, we earned \$5.0 million, \$9.0 million, \$15.0 million and \$10.0 million, respectively, upon achievement of non-refundable milestones anticipated in the Wyeth Collaboration; the first in connection with the commencement of a phase 3 clinical trial of the intravenous formulation of RELISTOR, the second in connection with the submission and acceptance for review of an NDA for a subcutaneous formulation of RELISTOR with the FDA and a comparable submission in the European Union, the third for the FDA approval of subcutaneous RELISTOR and the fourth for the European approval of subcutaneous RELISTOR. We considered those milestones to be substantive based on the significant degree of risk at the inception of the Collaboration related to the conduct and successful completion of clinical trials and, therefore, of not achieving the milestones; the amount of the payment received relative to the significant costs incurred since inception of the Wyeth Collaboration and amount of effort expended or the risk associated with the achievement of these milestones; and the passage of ten, 17, 28 and 31 months, respectively, from inception of the Collaboration to the achievement of those milestones. Therefore, we recognized the milestone payments as revenue in the respective periods in which the milestones were earned.

Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone and, therefore, the resulting payment would be considered part of the consideration and be recognized as revenue as such performance obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

We will 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 EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Royalty revenue is recognized based upon net sales of related licensed products, as reported to us by Wyeth. 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. If royalties are received when we have remaining performance obligations, they would be attributed to the services being provided under the arrangement and, therefore, recognized as such obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year of the balance sheet date are

classified as long-term deferred revenue. The estimate of the classification of deferred revenue as short-term or long-term is based upon management's current operating budget for the Wyeth Collaboration for our total effort required to complete our performance obligations under that arrangement. That estimate may change in the future and such changes to estimates would be accounted for prospectively and would result in a change in the amount of revenue recognized in future periods.

In October 2008, we entered into an exclusive license agreement with Ono under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan and under that agreement, in November 2008, we received from Ono an upfront payment of \$15.0 million. As of December 31, 2008, relative to the \$15.0 million upfront payment from Ono, we have recorded \$15.0 million as deferred revenue – current, which we expect to recognize as revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono is to own the subcutaneous filings and approvals relating to RELISTOR in Japan. We are also entitled to receive up to an additional \$20.0 million, payable upon achievement of 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. Supervision of and consultation with respect to Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer-related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them.

NIH grant and contract revenue is recognized as efforts are expended and as related subsidized project costs are incurred. We perform work under the NIH grants and contract on a best-effort basis. The NIH reimburses us for costs associated with projects in the fields of virology and cancer, including pre-clinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus, as requested by the NIH. Substantive at-risk milestone payments are uncommon in these arrangements, but would be recognized as revenue on the same basis as the Substantive Milestone Method.

**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 Statement of Financial Accounting Standards No. 123 (revised 2004) (FAS 123(R)) "Share-Based Payment." We account for share-based compensation to non-employees, including non-qualified stock options and restricted stock, in accordance with EITF Issue No. 96-18 "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Connection with Selling, Goods or Services."

We adopted FAS 123(R) using the modified prospective application, under which compensation cost for all share-based awards that were unvested as of January 1, 2006, the adoption date, and those newly granted or modified after the adoption date will be recognized in our financial statements over the related requisite service periods; usually the vesting periods for awards with a service condition. Compensation cost is based on the grant-date fair value of awards that are expected to vest. As of December 31, 2008, there was \$15.1 million, \$8.7 million and \$0.07 million of total unrecognized compensation cost related to non-vested stock options under the plans, the non-vested shares and the Purchase Plans, respectively. Those costs are expected to be recognized over weighted average periods of 2.6 years, 1.9 years and 0.04 years, respectively. 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. 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.

Under FAS 123(R), 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 of stock price on the date of grant, exercise price, volatility, expected term, dividend rate and risk-free interest rate. For this purpose:

- We use the closing price of our common stock on the date of grant, as quoted on The NASDAQ Stock Market LLC, as the exercise price.
- 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 the years ended December 31, 2008, 2007 and 2006, the volatility of our common stock has been high, 66%-91%, 50%-89% and 69%-94%, respectively, which is common for entities in the biotechnology industry that do not have commercial products. A higher volatility input to the Black-Scholes model increases the resulting compensation expense.

- The expected term of options granted represents the period of time that options granted are expected to be outstanding. For the years ended December 31, 2008 and 2007, our expected term was calculated based upon historical data related to exercise and post-termination cancellation activity. Accordingly, for grants made to employees and officers (excluding our Chief Executive Officer) and directors, we are using expected terms of 5.33 and 7.30 years and 5.25 and 7.5 years, respectively. Beginning in the third quarter of 2008, we estimated the expected term of stock options granted to our Chief Executive Officer to be 7.5 years. Expected term for options granted to non-employee consultants was ten years, which is the contractual term of those options. For the July 1, 2008 award, the Compensation Committee of the Board of Directors modified the form of the grant used for stock incentive awards to provide for vesting of stock incentive awards granted on that date ratably over a three-year period and for acceleration of the vesting of such awards and all previously granted and outstanding awards for any employee in the event that, following a Change in Control, such employee's employment is Terminated without Cause (as such terms are defined in our 2005 Stock Incentive Plan). For the year ended December 31, 2006, our expected term was calculated based upon the simplified method as detailed in SAB No. 107. Accordingly, we used an expected term of 6.5 years based upon the vesting period of the outstanding options of four or five years and a contractual term of ten years. A shorter expected term would result in a lower compensation expense.
- Since we have never paid dividends and do not expect to pay dividends in the future, 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.

A portion of the options granted to our Chief Executive Officer on July 1, 2002, 2003, 2004 and 2005, on July 3, 2006 and on July 2, 2007 cliff vests after nine years and eleven months from the respective grant date. The July 1, 2002, 2003 and 2005 awards have 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 FAS 123(R), 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. The requisite service period for the award is the shortest of the explicit or implied service periods. In the case of the executive's options, the explicit service period is nine years and eleven months from the respective grant dates. The implied service periods related to the performance conditions are the estimated times for each performance condition to be achieved. Thus, compensation expense will be recognized over the shortest estimated time for the achievement of performance conditions for that award (assuming that the performance conditions will be achieved before the cliff vesting occurs). On July 1, 2008, we granted options and restricted stock to our Chief Executive Officer which vest 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 while the restricted stock awards do not include an exercise price. The awards to our Chief Executive Officer are valued using a Monte Carlo simulation and the expense related to these grants 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.

The fair value of shares purchased under the Purchase Plans is estimated on the date of grant in accordance with Financial Accounting Standards Board (FASB) Technical Bulletin No. 97-1 "Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option." The same option valuation model is used for the Purchase Plans as for non-qualified stock options, except that the expected term for the Purchase Plans is six months and the historical volatility is calculated over the six month expected term.

In applying the treasury stock method for the calculation of diluted earnings per share (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 earnings per share calculation unless they are anti-dilutive. We incurred net losses for the years ended December 31, 2006, 2007 and 2008, and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for those periods. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculations, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

For the years ended December 31, 2006, 2007 and 2008, no tax benefit was recognized related to total compensation cost for share-based payment arrangements recognized in operations because we had a net loss for the period and the related deferred tax

assets were fully offset by a 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 years ended December 31, 2006, 2007 and 2008.

**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 expected 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 are expected 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. The Collaboration Agreement with Wyeth in which Wyeth has assumed all of the financial responsibility for further development, mitigates those costs. 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.

On January 1, 2008, we adopted EITF Issue 07-3 (EITF 07-3) “Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities.” Prior to January 1, 2008, under Statement of Financial Accounting Standards No. 2, “Accounting for Research and Development Costs,” non-refundable advance payments for future research and development activities for materials, equipment, facilities and purchased intangible assets that had no alternative future use were expensed as incurred. Beginning January 1, 2008, we have been capitalizing such non-refundable advance payments and expensing them as the goods are delivered or the related services are performed. EITF 07-3 applies to new contracts entered into after the effective date of January 1, 2008. The adoption of EITF 07-3 did not have a material impact on the financial position or results of operations.

**Fair Value Measurements.** Our available-for-sale investment portfolio consists of marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, and is recorded at fair value in the accompanying Consolidated Balance Sheets in accordance with Statement of Financial Accounting Standards No. 115, “Accounting for Certain Investments in Debt and Equity Securities.” The change in the fair value of these investments is recorded as a component of other comprehensive loss.

We adopted Statement of Financial Accounting Standards No. 159 (FAS 159) “The Fair Value Option of Financial Assets and Financial Liabilities” effective January 1, 2008, which provides companies with an option to report certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. FAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The objective of FAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. We have elected not to apply the fair value option to any of our financial assets or liabilities.

We also adopted Statement of Financial Accounting Standards No. 157 (FAS 157) “Fair Value Measurements” effective January 1, 2008 for financial assets and financial liabilities. FAS 157 defines fair value as the price that would be received to sell an asset or would be paid to transfer a liability (*i.e.*, the “exit price”) in an orderly transaction between market participants at the measurement date, and establishes a framework to make the measurement of fair value more consistent and comparable. In accordance with FASB Staff Position (FSP) No. FAS 157-2, “Effective Date of FASB Statement No. 157,” we will defer the adoption of FAS 157 for our nonfinancial assets and nonfinancial liabilities until January 1, 2009. We are currently evaluating the impact of FAS 157 for nonfinancial assets and nonfinancial liabilities, and currently do not expect the adoption of this deferral to have a material effect on our financial position or results of operations. The partial adoption of FAS 157 did not have a material impact on our fair value measurements.

FAS 157 established a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed based on market data obtained from sources independent of the reporting entity (“observable inputs”) and the reporting entity’s own assumptions about market participant assumptions developed based on 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.

### **Impact of Recently Issued Accounting Standards**

In March 2008, the FASB issued Statement of Financial Accounting Standards No. 161 (FAS 161) “Disclosures about Derivative Instruments and Hedging Activities – an amendment to FASB Statement No. 133,” which is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures. The enhanced disclosure conveys the purpose of derivative use to enable investors a better understanding of their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. We do not expect the effect of the adoption of FAS 161 to have a material effect on our financial position or results of operations.

In October 2008, the FASB issued FSP No. FAS 157-3 (FSP FAS 157-3) “Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active.” FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active and illustrates how an entity should determine fair value when the market for a financial asset is not active. FSP FAS 157-3 provides guidance on how an entity's own assumptions about cash flows and discount rates should be considered when measuring fair value when relevant market data do not exist, how observable market information in an inactive or dislocated market affects fair value measurements and how the use of broker and pricing service quotes should be considered when applying fair value measurements. FSP FAS 157-3 is effective immediately as of September 30, 2008 and for all interim and annual periods thereafter. The adoption of FSP FAS 157-3 did not have a material effect on our financial position or results of operations.

In June 2008, the FASB issued FSP EITF Issue No. 03-6-1 (FSP EITF 03-6-1) “Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities.” FSP EITF 03-6-1 requires entities to allocate earnings to unvested and contingently issuable share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents when calculating EPS and also present both basic EPS and diluted EPS pursuant to the two-class method described in Statement of Financial Accounting Standards No. 128, “Earnings Per Share.” FSP EITF 03-6-1 is effective January 1, 2009 and requires retrospective application. We are currently evaluating the impact this FSP will have on our financial statements.

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

Our primary investment objective is to preserve principal while maximizing yield without significantly increasing our risk. Our investments consist of taxable corporate debt securities, securities of government-sponsored entities and auction rate securities. Our investments totaled \$129.0 million at December 31, 2008. Approximately \$81.1 million of these investments had fixed interest rates, and \$47.9 million had interest rates that were variable. Our marketable securities are classified as available-for-sale.

Due to the conservative nature of our short-term fixed-interest-rate investments, we do not believe that we have a material exposure to interest-rate risk. Our fixed-interest-rate long-term investments are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair values of these investments due to differences between the market interest rate and the rate at the date of purchase of the investment. A 100 basis point increase in the December 31, 2008 market interest rates would result in a decrease of approximately \$0.03 million in the market values of these investments.

As a result of recent changes in general market conditions, we determined to reduce the principal amount of auction rate securities in our portfolio as they came up for auction and invest the proceeds in other securities in accordance with our investment guidelines. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. As a result, at December 31, 2008, we continue to hold approximately \$4.1 million (3% of assets measured at fair value) of auction rate securities, in respect of which we have received all scheduled interest payments, which, in the event of auction failure, are reset according to the contractual terms in the governing instruments. The principal amount of these remaining auction rate securities will not be accessible until a successful auction occurs, 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 its impact, if any, on the fair market value of our investments. If the auction rate securities market conditions do not recover, we may be required to record additional losses in 2009, which may affect our financial condition, cash flows and net loss. 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. As a result of the estimated fair value, we have determined a temporary impairment in the valuation of these securities of \$0.3 million for the year ended December 31, 2008. A 100 basis point increase to our internal analysis would result in an increase of approximately \$0.042 million in the temporary impairment of these securities as of the year ended December 31, 2008.

## **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 and Chief Financial Officer, 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.

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 Chief Executive Officer and our Chief Financial Officer, 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 Chief Executive Officer and Chief Financial Officer 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, 2008 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 defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as 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, and includes those 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, 2008. The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

**Item 9B. Other Information**

None.

### PART III

The information required by the Form 10-K Items listed in the following table will be included under the respective headings specified for such Items in our definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the SEC:

<b><u>Item of Form 10-K</u></b>	<b><u>Location in 2009 Proxy Statement</u></b>
<b>Item 10. Directors, Executive Officers and Corporate Governance</b>	<i>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.*</i> *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> ).
<b>Item 11. Executive Compensation</b>	<i>Executive Compensation. Compensation Committee Report. Compensation Committee Interlocks and Insider Participation.</i>
<b>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</b>	<i>Equity Compensation Plan Information. Security Ownership of Certain Beneficial Owners and Management.</i>
<b>Item 13. Certain Relationships and Related Transactions, and Director Independence</b>	<i>Certain Relationships and Related Transactions. Affirmative Determinations Regarding Director Independence and Other Matters.</i>
<b>Item 14. Principal Accounting Fees and Services</b>	<i>Fees Billed for Services Rendered by our Independent Registered Public Accounting Firm. Pre-approval of Audit and Non-Audit Services by the Audit Committee.</i>

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

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

*a) Documents filed as part of this Report:*

Consolidated Financial Statements of Progenics Pharmaceuticals, Inc.:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2007 and 2008

Consolidated Statements of Operations for the years ended December 31, 2006, 2007 and 2008

Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the years ended December 31, 2006, 2007 and 2008

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2007 and 2008

Notes to Consolidated Financial Statements

*b) Item 601 Exhibits*

Those exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately following the signature page hereof and preceding the exhibits filed herewith, and such listing is incorporated herein by reference.

**PROGENICS PHARMACEUTICALS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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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 financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Progenics Pharmaceuticals, Inc. and its subsidiaries at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, and on the Company's internal control over financial reporting based on our integrated 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 and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 and Note 3 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006, the manner in which it accounts for uncertainties in income taxes in 2007, and the manner in which it accounts for fair value measurements for its financial assets and financial liabilities in 2008.

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP  
New York, New York  
March 9, 2009

**PROGENICS PHARMACEUTICALS, INC.**

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

	December 31,	
	2007	2008
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,423	\$ 56,186
Marketable securities	120,000	63,127
Accounts receivable	1,995	1,337
Other current assets	3,111	3,531
Total current assets	135,529	124,181
Marketable securities	39,947	22,061
Fixed assets, at cost, net of accumulated depreciation and amortization	13,511	11,071
Restricted cash	552	520
Total assets	\$ 189,539	\$ 157,833
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,765	\$ 6,496
Deferred revenue — current	17,728	31,645
Other current liabilities	57	57
Total current liabilities	32,550	38,198
Deferred revenue — long term	9,131	-
Other liabilities	359	266
Total liabilities	42,040	38,464
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$.001 par value; 20,000,000 shares authorized; issued and outstanding — none		
Common stock, \$.0013 par value; 40,000,000 shares authorized; issued — 29,753,820 in 2007 and 30,807,387 in 2008	39	40
Additional paid-in capital	401,500	422,085
Accumulated deficit	(254,046)	(298,718)
Accumulated other comprehensive income (loss)	6	(1,297)
Treasury stock, at cost (zero shares in 2007 and 200,000 shares in 2008)	-	(2,741)
Total stockholders' equity	147,499	119,369
Total liabilities and stockholders' equity	\$ 189,539	\$ 157,833

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

**PROGENICS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(in thousands, except for loss per share data)**

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2007</b>	<b>2008</b>
<b>Revenues:</b>			
Research and development from collaborator	\$ 58,415	\$ 65,455	\$ 59,885
Royalty income	-	-	146
Research grants and contract	11,418	10,075	7,460
Other revenues	73	116	180
Total revenues	69,906	75,646	67,671
<b>Expenses:</b>			
Research and development	61,711	95,234	82,290
In-process research and development	13,209	-	-
License fees – research and development	390	942	2,830
General and administrative	22,259	27,901	28,834
Loss in joint venture	121	-	-
Royalty expense	-	-	15
Depreciation and amortization	1,535	3,027	4,609
Total expenses	99,225	127,104	118,578
Operating loss	(29,319)	(51,458)	(50,907)
<b>Other income:</b>			
Interest income	7,701	7,770	6,235
Total other income	7,701	7,770	6,235
Net loss	\$ (21,618)	\$ (43,688)	\$ (44,672)
Net loss per share - basic and diluted	\$ (0.84)	\$ (1.60)	\$ (1.51)
Weighted-average shares - basic and diluted	25,669	27,378	29,654

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

**PROGENICS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS**  
**For the Years Ended December 31, 2006, 2007 and 2008**  
**(in thousands)**

	Common Stock		Additional Paid-In Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total
	Shares	Amount					Shares	Amount	
<b>Balance at December 31, 2005</b>	25,229	\$ 33	\$ 306,085	\$ (4,498)	\$ (188,740)	\$ (148)	-	\$ -	\$112,732
Comprehensive loss:									
Net loss	-	-	-	-	(21,618)	-	-	-	(21,618)
Net change in unrealized gain on marketable securities	-	-	-	-	-	3	-	-	3
Total comprehensive loss:									(21,615)
Compensation expenses for share-based payment arrangements	-	-	12,034	-	-	-	-	-	12,034
Issuance of restricted stock, net of forfeitures	228	-	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	742	1	7,074	-	-	-	-	-	7,075
Issuance of compensatory stock options to non-employees	-	-	620	-	-	-	-	-	620
Elimination of unearned compensation upon adoption of FAS 123(R)	-	-	(4,498)	4,498	-	-	-	-	-
<b>Balance at December 31, 2006</b>	26,199	34	321,315	-	(210,358)	(145)	-	-	110,846
Comprehensive loss:									
Net loss	-	-	-	-	(43,688)	-	-	-	(43,688)
Net change in unrealized gain on marketable securities	-	-	-	-	-	151	-	-	151
Total comprehensive loss:									(43,537)
Compensation expenses for share-based payment arrangements	-	-	15,306	-	-	-	-	-	15,306
Issuance of restricted stock, net of forfeitures	267	-	-	-	-	-	-	-	-
Sale of common stock in a public offering (\$23.15 per share, net of underwriting discounts and commissions and other offering expenses of \$3,112) (see Note 8)	2,600	3	57,075	-	-	-	-	-	57,078
Sale of common stock under employee stock purchase plans and exercise of stock options	688	2	7,823	-	-	-	-	-	7,825
Repurchase of restricted stock	-	-	(19)	-	-	-	-	-	(19)
<b>Balance at December 31, 2007</b>	29,754	39	401,500	-	(254,046)	6	-	-	147,499
Comprehensive loss:									
Net loss	-	-	-	-	(44,672)	-	-	-	(44,672)
Net change in unrealized loss on marketable securities	-	-	-	-	-	(1,303)	-	-	(1,303)
Total comprehensive loss:									(45,975)
Compensation expenses for share-based payment arrangements	-	-	14,133	-	-	-	-	-	14,133
Issuance of restricted stock, net of forfeitures	216	-	-	-	-	-	-	-	-
Sale of common stock under employee stock purchase plans and exercise of stock options	837	1	6,452	-	-	-	-	-	6,453
Treasury shares acquired under repurchase program	-	-	-	-	-	-	(200)	(2,741)	(2,741)
<b>Balance at December 31, 2008</b>	30,807	\$ 40	\$ 422,085	\$ -	\$ (298,718)	\$ (1,297)	(200)	\$ (2,741)	\$ 119,369

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

**PROGENICS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years Ended December 31,		
	2006	2007	2008
Cash flows from operating activities:			
Net loss	\$ (21,618)	\$ (43,688)	\$ (44,672)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,535	3,027	4,609
Write-off of fixed assets	2	-	3
Amortization of discounts, net of premiums, on marketable securities	9	(445)	960
Expenses for share-based compensation awards	12,654	15,306	14,133
Expense of purchased technology	13,209	-	-
Loss in joint venture	121	-	-
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	1,588	(296)	658
(Increase) decrease in other current assets	(620)	70	(420)
Increase (decrease) in accounts payable and accrued expenses	1,533	2,913	(8,269)
Decrease in due to joint venture	(194)	-	-
Decrease in investment in joint venture	250	-	-
(Decrease) increase in deferred revenue	(16,910)	(16,231)	4,786
(Decrease) increase in other current liabilities	(790)	57	-
Increase (decrease) in other liabilities	74	236	(93)
Net cash used in operating activities	(9,157)	(39,051)	(28,305)
Cash flows from investing activities:			
Capital expenditures	(8,768)	(5,151)	(2,172)
Sales/maturities of marketable securities	267,934	252,850	128,705
Purchase of marketable securities	(299,075)	(275,048)	(56,209)
Acquisition of PSMA LLC, net of cash acquired	(13,128)	-	-
(Increase) decrease in restricted cash	(6)	(8)	32
Net cash (used in) provided by investing activities	(53,049)	(27,357)	70,356
Cash flows from financing activities:			
Proceeds from sale of common stock in public offering	-	60,190	-
Expenses related to the sale of common stock in public offering	-	(3,112)	-
Purchase of treasury stock	-	-	(2,741)
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	7,075	7,825	6,453
Repurchase of restricted stock	-	(19)	-
Net cash provided by financing activities	7,075	64,884	3,712
Net (decrease) increase in cash and cash equivalents	(55,125)	(1,524)	45,763
Cash and cash equivalents at beginning of period	67,072	11,947	10,423
Cash and cash equivalents at end of period	\$ 11,947	\$ 10,423	\$ 56,186
Supplemental disclosure of noncash investing activity:			
Fair value of assets, including purchased technology, acquired from PSMA LLC	\$ 13,674		
Cash paid for acquisition of PSMA LLC	(13,459)		
Liabilities assumed from PSMA LLC	\$ 215		

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

## PROGENICS PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

#### 1. Organization and Business

Progenics Pharmaceuticals, Inc. (“Progenics,” “we” or “us”) is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward supportive care, virology and oncology.

Progenics commenced principal operations in 1988 and in 2006 acquired full ownership of PSMA Development Company LLC (“PSMA LLC”) (see Note 12). Certain of our intellectual property rights are held by wholly owned subsidiaries. None of our subsidiaries other than PSMA LLC had operations during the years ended December 31, 2006, 2007 or 2008. Currently, all of our operations are conducted at our facilities in Tarrytown, New York. Our chief operating decision maker reviews financial analyses and forecasts relating to all of our research programs as a single unit and allocates resources and assesses performance of such programs as a whole. We operate under a single research and development segment.

##### *Supportive Care*

Our first commercial product, RELISTOR<sup>®</sup> (methylnaltrexone bromide), was approved by the U.S. Food and Drug Administration (“FDA”) for sale in the United States in April 2008. Our collaboration partner, Wyeth Pharmaceuticals (“Wyeth”), commenced sales of RELISTOR subcutaneous injection in June, and we have begun earning royalties on world-wide sales. Regulatory approvals have also been obtained in Canada, the European Union, Australia and Venezuela, and marketing applications have been approved or are pending or scheduled in other countries. In October, we out-licensed to Ono Pharmaceutical Co., Ltd., Osaka, Japan, the rights to subcutaneous RELISTOR in Japan. We continue development and clinical trials with respect to other indications for RELISTOR.

Development and commercialization of RELISTOR is being conducted under a license and co-development agreement (“Wyeth Collaboration Agreement”) between us and Wyeth (see Note 9). Under that agreement, we (i) have received an upfront payment from Wyeth, (ii) have received and are entitled to receive additional payments as certain developmental milestones for RELISTOR are achieved, (iii) have been and are entitled to be reimbursed by Wyeth for expenses we incur in connection with the development of RELISTOR under an agreed-upon development plan and budget, and (iv) have received and are entitled to receive royalties and commercialization milestone payments. Manufacturing and commercialization expenses for RELISTOR are funded by Wyeth.

In October 2006, we earned a \$5.0 million milestone payment in connection with the start of a phase 3 clinical trial of intravenous RELISTOR for the treatment of post-operative ileus (“POI”). In May 2007, we earned \$9.0 million, representing two milestone payments, under the Wyeth Collaboration Agreement for having made filings seeking marketing approval for RELISTOR subcutaneous injection in the U.S. and Europe. In April 2008, we earned a \$15.0 million milestone payment from Wyeth for the FDA approval of subcutaneous RELISTOR, and in July 2008, we earned a \$10.0 million milestone payment from Wyeth for European approval of subcutaneous RELISTOR.

We and Wyeth are also developing intravenous and oral formulations of RELISTOR.

Wyeth has elected, as it was entitled to do under our Collaboration, not to develop RELISTOR in Japan, and as provided in that Agreement returned to us the rights to RELISTOR in Japan. In October 2008, we entered into an exclusive License Agreement with Ono Pharmaceutical Co., Ltd. (“Ono”), Osaka, Japan under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan which we reacquired from Wyeth as a result of its election. Under that agreement, in November 2008, we received from Ono an upfront payment of \$15.0 million, and are entitled to receive potential development milestones of up to \$20.0 million, commercial milestones and royalties on sales by Ono of subcutaneous RELISTOR in Japan. Ono also 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.

## PROGENICS PHARMACEUTICALS, INC.

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

As a result of the return of the Japanese rights, we will not receive from Wyeth, milestone payments related to the development of RELISTOR formulations in Japan. These potential future milestone payments would have totaled \$22.5 million (of which \$7.5 million related to the subcutaneous formulation of RELISTOR and the remainder to the intravenous and oral formulations). Taking these adjustments into account, we now have the potential to receive a total of \$334.0 million in development and commercialization milestone payments from Wyeth under the Wyeth Collaboration Agreement (of which \$60.0 million relate to the intravenous formulation of RELISTOR), and of which \$39.0 million (\$5.0 million relating to the intravenous formulation) have been paid to date.

The payments described above will depend on continued success in development and commercialization of RELISTOR, which are in turn dependent on the actions of Wyeth, Ono, the FDA and other regulatory bodies, as well as the outcome of clinical and other testing of RELISTOR. Many of these matters are outside our control.

#### *Virology*

In the area of virology, we are developing two viral-entry inhibitors: a humanized monoclonal antibody, PRO 140, for treatment of human immunodeficiency virus (“HIV”), the virus that causes acquired immunodeficiency syndrome (“AIDS”), and a proprietary orally-available small-molecule drug candidate, designated PRO 206, for treatment of hepatitis C virus infection (“HCV”). We have recently selected for further clinical development the subcutaneous form of PRO 140 for treatment of HIV infection, which has the potential for convenient, weekly self-administration, and we are conducting preclinical development activities in preparation for filing an Investigational New Drug (“IND”) application for PRO 206. We are also engaged in research regarding prophylactic vaccines against HIV infection.

#### *Oncology*

In the area of prostate cancer, we are conducting a phase 1 clinical trial of a fully human monoclonal antibody-drug conjugate (“ADC”) directed against 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 also developing therapeutic vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are conducted through our wholly owned subsidiary, PSMA LLC.

Our virology and oncology product candidates are not as advanced in development as RELISTOR, and we do not expect any recurring revenues from sales or otherwise with respect to these product candidates in the near term. Wyeth’s agreement to reimburse us for RELISTOR development expenses enables us to devote current and future resources to other research and development programs.

#### *Corporate-Related Matters*

We may require additional funding to continue our operations. As a result, we may enter into a collaboration agreement, license or sale transaction or royalty sales or financings with respect to our products and product candidates. We may also seek to raise additional capital through the sale of our common stock or other securities and expect to fund certain aspects of our operations through government grants and contracts.

We have had recurring losses since our inception. At December 31, 2008, we had an accumulated deficit of \$298.7 million and had cash, cash equivalents and marketable securities, including non-current portion, totaling \$141.4 million. We expect that cash, cash equivalents and marketable securities at December 31, 2008 will be sufficient to fund current operations beyond one year. During the year ended December 31, 2008, we had a net loss of \$44.7 million and used cash in operating activities of \$28.3 million.

In April, 2008, our Board of Directors approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, funding for which comes from the \$15.0 million milestone payment we received from Wyeth related to U.S. marketing approval for RELISTOR. Purchases under the program are made at our discretion subject to market conditions in the open-market or otherwise, and in accordance with the regulations of the U.S. Securities and Exchange Commission (“SEC”), including Rule 10b-18. During the year ended December 31, 2008, we repurchased 200,000 of our outstanding common shares. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have \$12.3 million remaining available for purchases under the program.

## PROGENICS PHARMACEUTICALS, INC.

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

Pending use in our business, our revenues and proceeds of financing activities are held in cash, cash equivalents and marketable securities. Our marketable securities, which include corporate debt securities, securities of government-sponsored entities and auction rate securities, are classified as available-for-sale.

## 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 United States of America (“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.

Certain amounts have been reclassified in prior years’ financial statements to conform to the current presentation. This includes the reclassification of certain expenses from license fees-research and development to research and development which had no effect on total expenses as previously reported.

### Consolidation

The consolidated financial statements include the accounts of Progenics, as of and for the years ended December 31, 2006, 2007 and 2008, the balance sheet accounts of PSMA LLC as of December 31, 2007 and 2008 and the statement of operations accounts of PSMA LLC from April 20, 2006 to December 31, 2006 and for the years ended December 31, 2007 and 2008 (see Notes 1 and 12). 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”), Emerging Issues Task Force (“EITF”) Issue No. 00-21 (“EITF 00-21”) “Accounting for Revenue Arrangements with Multiple Deliverables” and EITF Issue No. 99-19 (“EITF 99-19”) “Reporting Revenue Gross as a Principal Versus Net as an Agent.” Our license and co-development agreement with Wyeth includes a non-refundable upfront license fee, reimbursement of development costs, research and development payments based upon our achievement of clinical development milestones, contingent payments based upon the achievement by Wyeth of defined events and royalties on product sales. We began recognizing research revenue from Wyeth on January 1, 2006. During the years ended December 31, 2008, 2007 and 2006, we also recognized revenue from government research grants and contract, which are used to subsidize a portion of certain of our research projects (“Projects”), exclusively from the National Institutes of Health (“NIH”). We also recognized revenue from the sale of research reagents during those periods.

Non-refundable upfront license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and steering or other committee services, can be separated in accordance with EITF 00-21. We would recognize upfront license payments as revenue upon delivery of the license only if the license had standalone value and the fair value of the undelivered performance obligations, typically including research or steering or other committee services, could be determined. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value, or (ii) have standalone value but the fair value of any of the undelivered performance obligations could not be determined, the upfront license payments would be recognized as revenue over the estimated period of when our performance obligations are performed.

We must determine the period over which our performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents will typically be used as the measure of performance. Under the

## PROGENICS PHARMACEUTICALS, INC.

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

proportionate performance method, revenue related to upfront license payments is recognized in any period as the percent of actual effort expended in that period relative to total effort for all of our performance obligations under the arrangement. We are recognizing revenue related to the upfront license payment we received from Wyeth using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Wyeth Collaboration Agreement based upon the most current budget approved by both Wyeth and us. Such performance obligations are provided by us on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. Since we have no obligation to develop the subcutaneous and intravenous formulations of RELISTOR outside the U.S. or the oral formulation at all and have no significant commercialization obligations for any product, recognition of revenue for the upfront payment is not required during those periods, if they extend beyond the period of our development obligations.

During the course of a collaboration agreement, *e.g.*, the Wyeth Collaboration Agreement, that involves a development plan and budget, the amount of the upfront license payment that is recognized as revenue in any period will increase or decrease as the percentage of actual effort increases or decreases, as described above. When a new budget is approved, generally annually, the remaining unrecognized amount of the upfront license fee will be recognized prospectively, using the methodology described above and applying any changes in the total estimated effort or period of development that is specified in the revised approved budget. The amounts of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 were based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amounts of revenue recognized in those periods. During the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased significantly based upon a revised development budget approved by both us and Wyeth. As a result, the period over which our obligations will extend, and over which the upfront payment will be amortized, was extended from the end of 2008 to the end of 2009. Consequently, the amount of revenue recognized from the upfront payment in the year ended December 31, 2008 declined relative to that in the comparable period of 2007. Due to the significant judgments involved in determining the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement, further changes in any of those judgments are reasonably likely to occur in the future which could have a material impact on our revenue recognition. If a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an upfront payment at the time of the termination.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement and the performance obligations are provided on a best-efforts basis, then the total upfront license payments would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations.

If we are involved in a steering or other committee as part of a multiple element 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. In relation to the Wyeth Collaboration Agreement, we have assessed the nature of our involvement with the Joint Steering Committee (“JSC”), Joint Development Committee (“JDC”) and Joint Commercialization Committee (“JCC”). Our involvement in the first two such committees is one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. We have combined the committee obligations with the other development obligations and are accounting for these obligations during the development phase as a single unit of accounting. After the development period, however, we have assessed the nature of our involvement with the committees to be a right, rather than an obligation. Our assessment is based upon the fact we negotiated to be on these committees as an accommodation for our granting of the license for RELISTOR to Wyeth. Further, Wyeth has been granted by us an exclusive license (even as to us) to the technology and know-how regarding RELISTOR and has been assigned the agreements for the manufacture of RELISTOR by third parties. Following regulatory approval of the subcutaneous and intravenous formulations of RELISTOR, Wyeth is obligated to continue to develop the oral formulation and to commercialize all formulations as provided in the Wyeth Collaboration Agreement, for which it is capable and responsible. During those periods, the activities of these committees will be focused on Wyeth’s development and commercialization obligations. As discussed in Note 1, Wyeth returned the rights to RELISTOR with respect to Japan to us in connection with its election not to develop RELISTOR there and the transaction with Ono. As a result, Wyeth is now responsible for the development of the oral formulation worldwide excluding Japan and the intravenous and subcutaneous formulations outside the U.S., other than Japan.

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

Collaborations may also contain substantive milestone payments. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (i) the milestone payment is non-refundable, (ii) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (iii) substantive effort is involved in achieving the milestone, (iv) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (v) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment (the “Substantive Milestone Method”). During October 2006, May 2007, April 2008 and July 2008, we earned \$5.0 million, \$9.0 million (two milestone payments), \$15.0 million and \$10.0 million, respectively, upon achievement of non-refundable milestones anticipated in the Wyeth Collaboration Agreement; the first in connection with the commencement of a phase 3 clinical trial of the intravenous formulation of RELISTOR, the second and third in connection with the submission and acceptance for review of an NDA for a subcutaneous formulation of RELISTOR with the FDA and a comparable submission in the European Union, the fourth for the FDA approval of subcutaneous RELISTOR and the fifth for the European approval of subcutaneous RELISTOR. We considered those milestones to be substantive based on the significant degree of risk at the inception of the Wyeth Collaboration Agreement related to the conduct and successful completion of clinical trials and, therefore, of not achieving the milestones; the amount of the payment received relative to the significant costs incurred since inception of the Collaboration and amount of effort expended or the risk associated with the achievement of these milestones; and the passage of ten, 17, 28 and 31 months, respectively, from inception of the Wyeth Collaboration Agreement to the achievement of those milestones. Therefore, we recognized the milestone payments as revenue in the respective periods in which the milestones were earned.

Determination as to whether a milestone meets the aforementioned conditions involves management’s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone and, therefore, the resulting payment would be considered part of the consideration and be recognized as revenue as such performance obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

We will 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 EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Royalty revenue is recognized based upon net sales of related licensed products, as reported to us by Wyeth. 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. If royalties are received when we have remaining performance obligations, they would be attributed to the services being provided under the arrangement and, therefore, recognized as such obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term deferred revenue. The estimate of the classification of deferred revenue as short-term or long-term is based upon management’s current operating budget for the Wyeth Collaboration Agreement for our total effort required to complete our performance obligations under that arrangement. That estimate may change in the future and such changes to estimates would be accounted for prospectively and would result in a change in the amount of revenue recognized in future periods.

In October 2008, we entered into an exclusive license agreement with Ono under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan and under that agreement, in November 2008, we received from Ono an upfront payment of \$15.0 million. As of December 31, 2008, relative to the \$15.0 million upfront payment from Ono, we have recorded \$15.0 million as deferred revenue – current, which we expect to recognize as revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono is to own the subcutaneous filings and approvals relating to RELISTOR in Japan. We are also entitled to receive up to an additional \$20.0 million, payable upon achievement of development milestones. Ono is also obligated to pay to us royalties and commercialization milestones on sales by Ono of

## PROGENICS PHARMACEUTICALS, INC.

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

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. Supervision of and consultation with respect to Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer-related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them.

NIH grant and contract revenue is recognized as efforts are expended and as related subsidized project costs are incurred. We perform work under the NIH grants and contract on a best-effort basis. The NIH reimburses us for costs associated with projects in the fields of virology and cancer, including pre-clinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus, as requested by the NIH. Substantive at-risk milestone payments are uncommon in these arrangements, but would be recognized as revenue on the same basis as the Substantive Milestone Method.

#### 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 the our clinical trials, clinical trial expenses, 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.

For each clinical trial that Progenics' conducts, certain costs, which are included in research and development expenses, are expensed based on the estimated period over which clinical investigators or contract research organizations provide services and total number of subjects in the trial including the estimated rate at which subjects enter the trial. 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 research and development 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 Per Share

We prepare our earnings per share ("EPS") data in accordance with Statement of Financial Accounting Standards No. 128 ("FAS 128") "Earnings Per Share." Basic net loss per share is computed on the basis of net loss for the period divided by the weighted average number of shares of common stock outstanding during the period, which includes restricted shares only as the restrictions lapse. 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.

#### Concentrations of Credit Risk

Financial instruments that potentially subject Progenics to concentrations of credit risk consist of cash, cash equivalents, marketable securities and receivables from Wyeth, Ono and the NIH. We invest our excess cash in money market funds, corporate

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

debt securities and federal agency issues. 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, 2007 and 2008, we have invested approximately \$4,249 and \$43,859, respectively, in cash equivalents in the form of money market funds with two major investment companies and held approximately \$6,174 and \$12,327, respectively, in a single commercial bank. Restricted cash represents amounts held in escrow for security deposits and credit cards.

#### Marketable Securities

In accordance with Statement of Financial Accounting Standards No. 115 (“FAS 115”) “Accounting for Certain Debt and Equity Securities,” investments are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income (loss). The amortized cost of debt securities in this category 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 marketable securities has been estimated based on quoted market prices. Interest and dividends on securities classified as available-for-sale are included in interest income (see Note 4).

At December 31, 2007 and 2008, our investment in marketable securities in the current and long term assets sections of the consolidated balance sheets included \$38.8 million and \$4.1 million, respectively, of auction rate securities. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders. 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. As a result of the estimated fair value, we have determined a temporary impairment in the valuation of these securities of \$0.3 million for the year ended December 31, 2008. All income generated from these current investments was recorded as interest income (see Note 4).

#### Fair Value Measurements

We adopted Financial Accounting Standards Board (“FASB”) Statement of Financial Accounting Standards No. 157 (“FAS 157”) “Fair Value Measurements” effective January 1, 2008 for financial assets and financial liabilities. FAS 157 defines fair value as the price that would be received to sell an asset or would be paid to transfer a liability (*i.e.*, the “exit price”) in an orderly transaction between market participants at the measurement date, and establishes a framework to make the measurement of fair value more consistent and comparable. In accordance with FASB Staff Position (“FSP”) No. FAS 157-2, “Effective Date of FASB Statement No. 157” we will defer the adoption of FAS 157 for our nonfinancial assets and nonfinancial liabilities until January 1, 2009. We are currently evaluating the impact of FAS 157 for nonfinancial assets and nonfinancial liabilities, and currently do not expect the adoption of this deferral to have a material effect on our financial position or results of operations. The partial adoption of FAS 157 did not have a material impact on our fair value measurements.

FAS 157 established a three-level hierarchy for fair value measurements that distinguishes between market participant assumptions developed based on market data obtained from sources independent of the reporting entity (“observable inputs”) and the reporting entity’s own assumptions about market participant assumptions developed based on 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.

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

- 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.

We also adopted Statement of Financial Accounting Standards No. 159 (“FAS 159”) “The Fair Value Option of Financial Assets and Financial Liabilities” effective January 1, 2008, which provides companies with an option to report certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. FAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The objective of FAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. We have elected not to apply the fair value option to any of our financial assets or liabilities.

#### Fixed Assets

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

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

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

#### 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 Statement of Financial Accounting Standards No. 144 “Accounting for the 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 the present value of the expected future cash flows associated with the use of the asset. No impairments occurred as of December 31, 2006, 2007 or 2008.

#### Income Taxes

We account for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No.109 (“FAS 109”) “Accounting for 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 connection with the adoption of Statement of Financial Accounting Standards No. 123 (revised 2004) (“FAS 123(R)”) “Share-Based Payment” which is a revision of Statement of Financial Accounting Standards No. 123 (“FAS 123”) “Accounting for Stock Based Compensation” (see Note 3), 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).

## PROGENICS PHARMACEUTICALS, INC.

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

Uncertain tax positions are accounted for in accordance with FASB Interpretation No. 48 (“FIN 48”) “Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement 109” which was adopted on January 1, 2007. FIN 48 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. FIN 48 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 its FIN 48 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 FIN 48. 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 FIN 48 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 14).

#### Risks and Uncertainties

We have to date generated only modest amounts of product and royalty revenue and except for RELISTOR, we have no products approved by the FDA for marketing. 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 the continued services of our current employees, consultants and subcontractors. In accordance with the Wyeth Collaboration Agreement and the Ono License, we have transferred to Wyeth and Ono the responsibility for manufacturing RELISTOR for clinical and commercial use in both bulk and finished form in their respective territories. Wyeth and Ono may not be able to fulfill its manufacturing obligations, either on its own or through third-party suppliers. For the years ended December 31, 2006, 2007 and 2008, the primary sources of our revenues were Wyeth and research grants and contract revenues from the NIH. There can be no assurance that revenues from Wyeth, Ono or from research grants and contract will continue. Beginning on January 1, 2006, we were no longer reimbursed by PSMA LLC for our services and we did not recognize revenue from PSMA LLC for the quarter ended March 31, 2006. Beginning in the second quarter of 2006, PSMA LLC became our wholly owned subsidiary and, accordingly, we no longer recognize revenue from PSMA LLC. Substantially all of our accounts receivable at December 31, 2007 and 2008 were from the above-named sources.

#### Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive loss includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The disclosures required by Statement of Financial Accounting Standards No. 130, “Reporting Comprehensive Income” for the years ended December 31, 2006, 2007 and 2008 have been included in the Statements of Stockholders’ Equity and Comprehensive Loss. There was no income tax expense/benefit allocated to any component of Other Comprehensive Loss (see Note 14).

#### Impact of Recently Issued Accounting Standards

In March 2008, the FASB issued Statement of Financial Accounting Standards No. 161 (“FAS 161”) “Disclosures about Derivative Instruments and Hedging Activities – an amendment to FASB Statement No. 133” which is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures. The enhanced disclosure conveys the purpose of derivative use to enable investors a better understanding of their effects on an entity’s financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (iii) how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. We do not expect the effect of the adoption of FAS 161 to have a material effect on our financial position or results of operations.

## PROGENICS PHARMACEUTICALS, INC.

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

In October 2008, the FASB issued FSP No. FAS 157-3 (“FSP FAS 157-3”), “Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active.” FSP FAS 157-3 clarifies the application of FAS 157 in a market that is not active and illustrates how an entity should determine fair value when the market for a financial asset is not active. FSP FAS 157-3 provides guidance on how an entity’s own assumptions about cash flows and discount rates should be considered when measuring fair value when relevant market data do not exist, how observable market information in an inactive or dislocated market affects fair value measurements and how the use of broker and pricing service quotes should be considered when applying fair value measurements. FSP FAS 157-3 is effective immediately as of September 30, 2008 and for all interim and annual periods thereafter. The adoption of FSP FAS 157-3 did not have a material effect on our financial position or results of operations.

In June 2008, the FASB issued FSP EITF Issue No. 03-6-1 (“FSP EITF 03-6-1”) “Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities.” FSP EITF 03-6-1 requires entities to allocate earnings to unvested and contingently issuable share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents when calculating EPS and also present both basic EPS and diluted EPS pursuant to the two-class method described in FAS 128. FSP EITF 03-6-1 is effective January 1, 2009 and requires retrospective application. We are currently evaluating the impact this FSP will have on our financial statements.

### 3. Share-Based Payment Arrangements

On January 1, 2006, we adopted FAS 123(R) which supersedes APB Opinion No. 25 (“APB 25”) “Accounting for Stock Issued to Employees,” and amends Statement of Financial Accounting Standards No. 95 “Statement of Cash Flows.” Our share-based payment arrangements with employees include non-qualified stock options, restricted stock and shares issued under Employee Stock Purchase Plans, which are compensatory under FAS 123(R), as described below. We account for share-based payment arrangements with non-employees, including non-qualified stock options and restricted stock, in accordance with EITF Issue No. 96-18 “Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Connection with Selling, Goods or Services” which accounting is unchanged as a result of the our adoption of FAS 123(R).

We adopted FAS 123(R) using the modified prospective application, under which compensation cost for all share-based awards that were unvested as of the adoption date and those newly granted or modified after the adoption date are being recognized over the related requisite service period, usually the vesting period 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 is recognized on a straight-line basis over the total requisite service period for the total award. Upon adoption of FAS 123(R), we eliminated \$4,498 of unearned compensation, related to share-based awards granted prior to the adoption date that were unvested as of January 1, 2006, against additional paid-in capital. The cumulative effect of adjustments upon adoption of FAS 123(R) was not material. Compensation expense recorded on a pro forma basis for periods prior to adoption of FAS 123(R) is not revised and is not reflected in the financial statements of those prior periods.

We have adopted four stock incentive plans, the 1989 Non-Qualified Stock Option Plan, the 1993 Stock Option Plan, the 1996 Amended Stock Incentive Plan and the 2005 Stock Incentive Plan (the “Plans”). Under each of these Plans as amended, a maximum of 375, 750, 5,000 and 3,950 shares of common stock, respectively, are available for awards to employees, consultants, directors and other individuals who render services to Progenics (collectively, “Awardees”). The Plans contain certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment as defined. The 1989 Plan and 1993 Plan provide for the Board, or the Compensation Committee (“Committee”) of the Board, to grant stock options to Awardees and to determine the exercise price, vesting term and expiration date. The 1996 Plan and the 2005 Plan provide 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 four to ten years and have terms of ten to twenty years. Restricted stock issued under the 1996 Plan or 2005 Plan usually vests annually over a four year period, 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, 2006, 2007 and 2008, all outstanding stock options were non-qualified options. The 1989, 1993 and 1996 Plans terminated in April 1994, December 2003 and October 2006, respectively, and 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.

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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.

Under FAS 123(R), the fair value of each option award granted under the Plans is estimated on the date of grant using the Black-Scholes option pricing model with the 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 method; 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 the year ended December 31, 2008 and 2007, expected term was calculated based upon historical data related to exercise and post-termination cancellation activity. Accordingly, for grants made to employees and officers (excluding our Chief Executive Officer) and directors, we are using expected terms of 5.33 and 7.30 years, and 5.25 and 7.5 years, respectively. Expected term for options granted to non-employee consultants was ten years, which is the contractual term of those options. The expected term of options granted in 2006 was based upon the simplified method of calculating expected term, as detailed in SAB No. 107 and represents the period of time that options granted are expected to be outstanding. Accordingly, we used an expected term of 6.5 years based upon the vesting period of the outstanding options of four or five years and a contractual term of ten years. 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 option is based on the U.S. Treasury yield curve in effect at the time of grant.

	<b>For the Years Ended December 31,</b>		
	<b>2006</b>	<b>2007</b>	<b>2008</b>
Expected volatility	69% - 94%	50% - 89%	66% - 91%
Expected dividends	zero	zero	zero
Expected term (years)	6.5	5.25 - 10	5.33 - 10
Weighted average expected term (years)	6.5	6.90	6.78
Risk-free rate	4.56% - 5.06%	3.88% - 4.93%	1.69% - 3.79%

A summary of option activity under the Plans as of December 31, 2008 and changes during the year then ended is presented below:

<b>Options</b>	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Yr.)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2008	4,708	\$18.14		
Granted	599	16.01		
Exercised	(172)	7.25		
Forfeited or expired	(684)	14.86		
Outstanding at December 31, 2008	4,451	\$18.78	5.81	\$1,104
Exercisable at December 31, 2008	3,247	\$18.06	4.88	\$1,101

The weighted average grant-date fair value of options granted under the Plans during the years ended December 31, 2006, 2007 and 2008 was \$19.32, \$16.18 and \$10.09, respectively. The total intrinsic value of options exercised during the years ended December 31, 2006, 2007 and 2008 was \$6,591, \$3,766 and \$969, respectively.

The options granted under the Plans, described above, include 33, 113, 38, 75, 145 and 113 non-qualified stock options granted to our Chief Executive Officer 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 eleven months from the respective grant dates. The July 1, 2002, 2003 and 2005 awards were

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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. Upon adoption of FAS 123(R) on January 1, 2006, 21, zero, 8 and 36 options were unvested under the 2002, 2003, 2004 and 2005 awards, respectively. In accordance with FAS 123(R), at the end of each reporting 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. In the case of the Chief Executive Officer's options, the explicit service period is nine years and eleven months from the respective grant dates. The implied service periods related to the performance conditions are the estimated times for each performance condition to be achieved. Thus, compensation expense will be recognized over the shortest estimated time for the achievement of performance conditions for that award (assuming that the performance conditions will be achieved before the cliff vesting occurs). To the extent that, for each of the 2004, 2006 and 2007 awards, it is probable that 100% of the remaining unvested award will vest based on achievement of the remaining performance conditions, compensation expense will be recognized over the estimated periods of achievement. To the extent that it is probable that less than 100% of the award will vest based upon remaining performance conditions, the shortfall will be recognized through the remaining period to nine years and eleven months from the grant date (*i.e.*, the remaining service period). Changes in the estimate of probability of achievement of any performance condition will be reflected in compensation expense of the period of change and future periods affected by the change. On July 1, 2008, we granted options and restricted stock to our Chief Executive Officer. The options have an exercise price equal to the closing price on our common stock on the date of grant while the restricted stock awards do not include an exercise price. Both options and restricted stock granted vest on the basis of the achievement of specified performance based milestones or market conditions. Compensation expense, for the July 1, 2008 award to our Chief Executive Officer, 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, 2008, the estimated requisite service periods for the 2004, 2006 and 2007 awards, described above, were 1.5, 7.5 and 8.5 years, respectively. For the year ended December 31, 2008, 33, 6, 7 and 56 options vested under the 2002, 2004, 2006 and 2007 awards, respectively, which resulted in compensation expense of \$17, \$7, \$607 and \$514, respectively. The reduction in compensation expense recognized for the 2006 award resulted from a change in the estimate of the period of vesting of the related performance milestones, as described above. Prior to the adoption of FAS 123(R), these awards were accounted for as variable awards under APB 25 and, therefore, compensation expense, based on the intrinsic value of the vested awards on each reporting date, was recognized in our financial statements.

A summary of the status of our restricted stock awarded under the Plans which has not yet vested as of December 31, 2008 and changes during the year then ended is presented below:

<b>Restricted Stock Awards</b>	<b>Shares</b>	<b>Weighted Average Grant- Date Fair Value</b>
Nonvested at January 1, 2008	523	\$22.35
Granted	264	14.37
Vested	(174)	21.74
Forfeited	(47)	22.49
Nonvested at December 31, 2008	566	\$18.81

During 1993, we adopted an Executive Stock Option Plan (the "Executive Plan"), under which a maximum of 750 shares of common stock, adjusted for stock splits, stock dividends and other capital adjustments, are available for stock option awards. Awards issued under the Executive Plan may qualify as ISO's, as defined by the Internal Revenue Code, or may be granted as non-qualified stock options. Under the Executive Plan, our Board of Directors may award options to senior executive employees (including officers who may be Board of Directors' members) of Progenics. The Executive Plan terminated on December 15, 2003; any options outstanding as of the termination date shall remain outstanding until such option expires in accordance with the terms of the respective grant. During December 1993, the Board of Directors awarded a total of 750 stock options under the Executive Plan to our current Chief Executive Officer, of which 665 were non-qualified options ("NQOs") and 85 were ISO's. The ISO's have been exercised in December 1998. The NQOs have a term of 14 years and entitle the officer to purchase shares of

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common stock at \$5.33 per share, which represented the estimated fair market value, of our common stock at the date of grant, as determined by the Board of Directors. As of December 31, 2007, there were no outstanding options under the Executive Plan. The total intrinsic value of NQOs under the Executive Plan exercised during the years ended December 31, 2006 and 2007 was \$4,662 and \$4,402, respectively.

Our 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, provide for the issuance of up to 2,400 and 600 shares of common stock, respectively. The Purchase Plans provide for the grant to all employees of options to use an amount equal to up to 25% of their quarterly compensation, as such percentage is 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 are granted automatically on the first day of each fiscal quarter and expire six months after the date of grant. The Qualified Plan is not available to employees owning more than five percent of the common stock and imposes certain other quarterly limitations on the option grants. Options under the Non-Qualified Plan are granted to the extent that option grants are restricted under the Qualified Plan.

The fair value of shares purchased under the Purchase Plans is estimated on the date of grant in accordance with FASB Technical Bulletin No. 97-1 “Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option,” using the same option valuation model used for options granted under the Plans, except that the assumptions noted in the following table were used for the Purchase Plans:

	<b>For the Years Ended December 31,</b>		
	<b>2006</b>	<b>2007</b>	<b>2008</b>
	Expected volatility	37% - 43%	40% - 46%
Expected dividends	zero	zero	zero
Expected term	6 months	6 months	6 months
Risk-free rate	3.25% - 4.75%	3.91% - 5.10%	0.14% - 2.74%

Purchases of common stock under the Purchase Plans during the years ended December 31, 2006, 2007 and 2008 are summarized as follows:

	<b>Qualified Plan</b>			<b>Non-Qualified Plan</b>		
	<b>Shares Purchased</b>	<b>Price Range</b>	<b>Weighted Average Grant- Date Fair Value</b>	<b>Shares Purchased</b>	<b>Price Range</b>	<b>Weighted Average Grant- Date Fair Value</b>
2006	126	\$17.80 - \$25.84	\$3.30	27	\$18.61 - \$25.84	\$3.25
2007	179	\$16.27 - \$23.46	\$3.41	45	\$17.80 - \$23.46	\$3.43
2008	538	\$4.26 - \$15.32	\$4.44	127	\$6.07 - \$15.32	\$4.83

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 the years ended December 31, 2006, 2007 and 2008 was:

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2007</b>	<b>2008</b>
<i>Recognized as:</i>			
Research and Development	\$5,814	\$7,104	\$7,241
General and Administrative	6,840	8,202	6,892
Total	\$12,654	\$15,306	\$14,133

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No tax benefit was recognized related to such compensation cost because we had a net loss for the periods presented and the related deferred tax assets were fully offset by valuation allowances. 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, 2008, there was \$15.1 million, \$8.7 million and \$0.07 million of total unrecognized compensation cost related to nonvested stock options under the Plans, the nonvested shares and the Purchase Plans, respectively. Those costs are expected to be recognized over weighted average periods of 2.6 years, 1.9 years and 0.04 years, respectively. Cash received from exercises under all share-based payment arrangements for the year ended December 31, 2008 was \$6.5 million. No tax benefit was realized for the tax deductions from those option exercises of the share-based payment arrangements because we had a net loss for the period and the related deferred tax assets were fully offset by a valuation allowance. 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 earnings per share calculation unless they are anti-dilutive. We incurred a net loss for the years ended December 31, 2006, 2007 and 2008 and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for those periods. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculations, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

**4. Fair Value Measurements and Marketable Securities**

Progenics considers its marketable securities to be “available-for-sale,” as defined by FAS 115 and, accordingly, unrealized holding gains and losses are excluded from operations and reported as a net amount in a separate component of stockholders’ equity (see Note 2). Our available-for-sale investment portfolio consists of marketable securities, which include money market funds, corporate debt securities, securities of government-sponsored entities and auction rate securities, and is recorded at fair value in the accompanying Consolidated Balance Sheets.

Marketable securities consisted of the following:

	<b>December 31, 2007</b>	<b>December 31, 2008</b>
	<u>                    </u>	<u>                    </u>
<i>Short-term</i>		
Corporate debt securities and securities of government-sponsored entities	\$ 81,170	\$ 63,127
Auction rate securities	38,830	-
Total short-term marketable securities	<u>120,000</u>	<u>63,127</u>
<i>Long-term</i>		
Corporate debt securities and securities of government-sponsored entities	39,947	18,002
Auction rate securities	-	4,059
Total long-term marketable securities	<u>39,947</u>	<u>22,061</u>
Total marketable securities	<u>\$ 159,947</u>	<u>\$ 85,188</u>

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The following table presents our available-for-sale investments measured at fair value on a recurring basis as of December 31, 2008 classified by the FAS 157 valuation hierarchy (as previously discussed):

<u>Description</u>	<u>Balance at December 31, 2008</u>	<u>Fair Value Measurements at Reporting Date Using</u>		
		<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
Money market funds	\$ 43,859	\$ 43,859	\$ -	\$ -
Corporate debt securities and securities of government-sponsored entities	81,129	-	81,129	-
Auction rate securities	4,059	-	-	4,059
Total	<u>\$ 129,047</u>	<u>\$ 43,859</u>	<u>\$ 81,129</u>	<u>\$ 4,059</u>

At December 31, 2008, we hold \$4.1 million in auction rate securities which are classified as Level 3 (3% of total assets measured at fair value). Auction rate securities are collateralized long-term instruments that provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined intervals, typically every 7 to 35 days. Beginning in February 2008, auctions failed for certain of our auction rate securities because sell orders exceeded buy orders, and we were unable to dispose of those securities at auction. The funds associated with these failed auctions will not be accessible until a successful auction occurs, the issuer calls or restructures the security, the security matures and is paid or a buyer outside the auction process emerges. The fair value of the auction rate securities we hold includes \$3.0 million of securities collateralized by student loan obligations subsidized by the U.S. government and \$1.1 million of investment company preferred stock, and do not include mortgage-backed instruments. As of December 31, 2008, 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 internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. As a result of the estimated fair value, we have determined a temporary impairment in the valuation of these securities of \$0.3 million, recorded for the year ended December 31, 2008, which is reflected as a part of other comprehensive loss on our balance sheet. These securities are held "available-for-sale" in conformity with FAS 115 and the unrealized loss is included in other comprehensive loss in the current period. 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 balance sheet.

We continue to monitor markets for our investments and consider its impact, if any, on the fair market value of our investments. If the market conditions for our investments do not recover, we may be required to record additional losses in 2009. We believe we will have the ability to hold any of our investments until their markets recover. We do not anticipate having to sell these securities in order to operate our business. 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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For those financial instruments with significant Level 3 inputs (all of which are auction rate securities), the following tables summarize the activities for the year ended December 31, 2008:

<u>Description</u>	<u>Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Year Ended December 31, 2008</u>	
Balance at beginning of period	\$	-
Transfers into Level 3		8,150
Total realized/unrealized gains (losses)		
Included in net loss		-
Included in comprehensive income (loss)		(316)
Settlements		(3,775)
Balance at end of period	\$	4,059
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	\$	(316)

The following table summarizes the amortized cost basis, the aggregate fair value and gross unrealized holding gains and losses at December 31, 2007 and 2008:

	<u>Amortized Cost Basis</u>	<u>Fair Value</u>	<u>Unrealized Holding</u>		
			<u>Gains</u>	<u>(Losses)</u>	<u>Net</u>
<b>2007:</b>					
Maturities less than one year:					
Corporate debt securities	\$76,853	\$76,892	\$84	\$(45)	\$39
Government-sponsored entities	4,295	4,278	-	(17)	(17)
Maturities between one and five years:					
Corporate debt securities	39,963	39,947	64	(80)	(16)
Maturities greater than ten years:					
Auction rate securities	27,130	27,130	-	-	-
Investments without stated maturity dates:					
Auction rate securities	11,700	11,700	-	-	-
	<u>\$159,941</u>	<u>\$159,947</u>	<u>\$148</u>	<u>\$(142)</u>	<u>\$6</u>
	<u>Amortized Cost Basis</u>	<u>Fair Value</u>	<u>Unrealized Holding</u>		
			<u>Gains</u>	<u>(Losses)</u>	<u>Net</u>
<b>2008:</b>					
Maturities less than one year:					
Corporate debt securities	\$63,982	\$63,127	\$114	\$(969)	\$(855)
Maturities between one and five years:					
Corporate debt securities	17,129	16,995	71	(205)	(134)
Government-sponsored entities	999	1,007	8	-	8
Maturities greater than ten years:					
Auction rate securities	3,200	2,944	-	(256)	(256)
Investments without stated maturity dates:					
Auction rate securities	1,175	1,115	-	(60)	(60)
	<u>\$86,485</u>	<u>\$85,188</u>	<u>\$193</u>	<u>\$(1,490)</u>	<u>\$(1,297)</u>

Progenics' computes 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.

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The following table shows the gross unrealized losses and fair value of Progenics' marketable 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, 2007 and 2008.

**At December 31, 2007:**

<u>Description of Securities</u>	<u>Less than 12 Months</u>		<u>12 Months or Greater</u>		<u>Total</u>	
	<u>Fair Value</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>	<u>Unrealized Losses</u>
Corporate debt securities	\$50,511	\$(118)	\$9,479	\$(7)	\$59,990	\$(125)
Government-sponsored entities	4,278	(17)			4,278	(17)
Total	<u>\$54,789</u>	<u>\$(135)</u>	<u>\$9,479</u>	<u>\$(7)</u>	<u>\$64,268</u>	<u>\$(142)</u>

**At December 31, 2008:**

<u>Description of Securities</u>	<u>Less than 12 Months</u>		<u>12 Months or Greater</u>		<u>Total</u>	
	<u>Fair Value</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>	<u>Unrealized Losses</u>
Corporate debt securities	\$57,567	\$(1,174)	\$-	\$-	\$57,567	\$(1,174)
Auction rate securities	4,059	(316)			4,059	(316)
Total	<u>\$61,626</u>	<u>\$(1,490)</u>	<u>\$-</u>	<u>\$-</u>	<u>\$61,626</u>	<u>\$(1,490)</u>

**Corporate debt securities.** Progenics' investments in corporate debt securities with unrealized losses at December 31, 2008 include 34 securities with maturities of less than one year (\$46,028 of the total fair value and \$969 of the total unrealized losses in corporate debt securities) and 9 securities with maturities between one and two years (\$11,539 of the total fair value and \$205 of the total unrealized losses in corporate debt securities). The severity of the unrealized losses (fair value is approximately 0.00563 percent to 17.67 percent less than cost) and duration of the unrealized losses (weighted average of 6.98 months) correlate with the short maturities of the majority of these investments. The increase in unrealized losses in 2008 was attributable to our purchase of corporate debt securities, trading at a premium in early 2008, which declined in market value at the end of 2008. Our corporate debt securities are purchased by third-party brokers in accordance with its investment policy guidelines. Our brokerage account requires that all corporate debt securities be held to maturity unless authorization is obtained from us to sell earlier. In fact, Progenics' has a history of holding corporate debt securities to maturity. Progenics', therefore, considers that it has the intent and ability to hold any corporate debt securities with unrealized losses until a recovery of fair value, which may be maturity and it does not consider these marketable securities to be other-than-temporarily impaired at December 31, 2008.

**Auction rate securities.** The unrealized losses on Progenics' investments in auction rate securities during a period of less than 12 months were the result of an internal analysis of timing of expected future successful auctions, collateralization of underlying assets of the security and credit quality of the security. The severity of the unrealized losses (fair value is approximately 6 percent to 8 percent less than cost) and duration of the unrealized losses (weighted average of 9.25 months) correlate with the short maturities of these investments. Similar to corporate debt securities, discussed above, Progenics' considers that it has the intent and ability to hold any investments in auction rate securities with unrealized losses until a recovery of fair value, which may be maturity or a successful auction and it does not consider these marketable securities to be other-than-temporarily impaired at December 31, 2008.

**5. Accounts Receivable**

	<u>December 31,</u>	
	<u>2007</u>	<u>2008</u>
National Institutes of Health	\$ 1,956	\$ 1,107
Royalties	-	229
Other	39	1
Total	<u>\$ 1,995</u>	<u>\$ 1,337</u>

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — continued**  
(amounts in thousands, except per share amounts or unless otherwise noted)

**6. Fixed Assets**

	December 31,	
	2007	2008
Computer equipment	\$ 1,935	\$ 2,335
Machinery and equipment	11,695	13,161
Furniture and fixtures	726	750
Leasehold improvements	10,448	10,546
Construction in progress	874	907
	25,678	27,699
Less, accumulated depreciation and amortization	(12,167)	(16,628)
Total	\$ 13,511	\$ 11,071

At December 31, 2007, \$5.7 million, \$0.9 million and \$0.7 million of leasehold improvements were being amortized over periods of 2.3 – 5.8 years, 4.7 years and 8.5 years, respectively, under leases with terms through December 31, 2009, June 29, 2012 and December 31, 2014, respectively. At December 31, 2008, \$5.8 million, \$0.9 million and \$0.7 million of leasehold improvements were being amortized over periods of 1.0 – 5.8 years, 4.0 – 4.7 years and 8.5 years, respectively, under the same respective leases.

**7. Accounts Payable and Accrued Expenses**

	December 31,	
	2007	2008
Accounts payable	\$ 1,158	\$ 899
Accrued consulting and clinical trial costs	10,848	3,556
Accrued payroll and related costs	1,489	1,093
Legal and professional fees	1,127	925
Other	143	23
Total	\$ 14,765	\$ 6,496

**8. Stockholders' Equity**

We are authorized to issue 40,000 shares of common stock, par value \$.0013 (“Common Stock”), and 20,000 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.

On September 25, 2007, we completed a public offering of 2.6 million shares of our Common Stock, pursuant to a shelf registration statement that had been filed with the SEC in 2006, which had registered 4.0 million shares of our Common Stock. We received proceeds of \$57.3 million, or \$22.04 per share, which was net of underwriting discounts and commissions of approximately \$2.9 million, and paid approximately \$0.2 million in other offering expenses.

In connection with the adoption of FAS 123(R) on January 1, 2006, we eliminated \$4,498 of unearned compensation, related to share-based awards granted prior to the adoption date that were unvested as of that date, against additional paid-in-capital.

On April 24, 2008, our Board of Directors approved a share repurchase program to acquire up to \$15.0 million of our outstanding common shares, funding for which comes from the \$15.0 million milestone payment we received from Wyeth related to U.S. marketing approval for RELISTOR. Purchases under the program are made at our discretion subject to market conditions in the open-market or otherwise, and in accordance with the regulations of the SEC, including Rule 10b-18. During the year ended December 31, 2008, we have repurchased 200,000 of our outstanding common shares for a total of \$2.7 million. Purchases may be discontinued at any time. Reacquired shares will be held in treasury until redeployed or retired. We have \$12.3 million remaining available for purchases under the program.

## PROGENICS PHARMACEUTICALS, INC.

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

#### 9. License Agreements with Wyeth Pharmaceuticals and Ono Pharmaceutical

On December 23, 2005, we entered into our Collaboration Agreement with Wyeth for the purpose of developing and commercializing RELISTOR. The Wyeth Collaboration Agreement involves three formulations of RELISTOR: (i) a subcutaneous formulation to be used in patients with OIC, (ii) an intravenous formulation to be used in patients with POI and (iii) an oral formulation to be used in patients with OIC.

The Wyeth Collaboration Agreement establishes the JSC and JDC, each with an equal number of representatives from both Wyeth and us. The JSC is responsible for coordinating the companies' key activities, while the JDC oversees, coordinates and expedites the development of RELISTOR by Wyeth and us. A JCC, composed of company representatives in number and function according to our respective responsibilities, facilitates open communication between Wyeth and us on commercialization matters.

We have assessed the nature of our involvement with the committees. Our involvement in the JSC and JDC is one of several obligations to develop the subcutaneous and intravenous formulations of RELISTOR through regulatory approval in the U.S. We have combined the committee obligations with the other development obligations and are accounting for these obligations during the development phase as a single unit of accounting. After the period during which we have developmental responsibilities, however, we have assessed that the nature of our involvement with the committees will be a right, rather than an obligation. Our assessment is based upon the fact that we negotiated to be on the committees as an accommodation for our granting of the license for RELISTOR to Wyeth. Wyeth has been granted by us an exclusive license (even as to us) to the technology and know-how regarding RELISTOR and has been assigned the agreements for the manufacture of RELISTOR by third parties. During that period, the activities of the committees will be focused on Wyeth's development and commercialization obligations.

Under the Wyeth Collaboration Agreement, we granted to Wyeth an exclusive, worldwide license, even as to us, to develop and commercialize RELISTOR. Wyeth returned the rights with respect to Japan to us in connection with its election not to develop RELISTOR there and the transaction with Ono discussed in Note 1, above. We are responsible for developing the subcutaneous and intravenous formulations in the U.S. until they receive regulatory approval, while Wyeth is responsible for these formulations outside the U.S. other than Japan. Wyeth is also responsible for the development of the oral formulation worldwide excluding Japan. We have transferred to Wyeth all existing supply agreements with third parties for RELISTOR and have sublicensed intellectual property rights to permit Wyeth to manufacture or have manufactured RELISTOR, during the development and commercialization phases of the Wyeth Collaboration Agreement, in both bulk and finished form for all products worldwide. We have no further manufacturing obligations under the Collaboration. We have and will continue to transfer to Wyeth all know-how, as defined, related to RELISTOR. Based upon our research and development programs, such period will cease upon completion of our development obligations under the Wyeth Collaboration Agreement.

In the event the JSC approves for development any formulation of RELISTOR other than subcutaneous, intravenous or oral or any other indication for a product using any formulation of RELISTOR, Wyeth is obligated to be responsible for development of such products as provided in the Wyeth Collaboration Agreement, including conducting clinical trials and obtaining and maintaining regulatory approval. Wyeth is also responsible for the commercialization of the subcutaneous, intravenous and oral products, and any other methylaltraxone based products developed upon approval by the JSC, throughout the world excluding Japan. Wyeth is obligated to pay all costs of commercialization of all products, including manufacturing costs, and will retain all proceeds from the sale of the products, subject to the royalties payable by Wyeth to us. Decisions with respect to commercialization of any products developed under the Wyeth Collaboration Agreement are to be made solely by Wyeth.

Wyeth granted to us an option (the "Co-Promotion Option") to enter into a Co-Promotion Agreement to co-promote any of the products developed under the Wyeth Collaboration Agreement, at any time, subject to certain conditions. We may exercise this option on an annual basis. We did not exercise the option in connection with the initial commercialization of RELISTOR, and as of December 31, 2008 have not determined when we will exercise it, if at all. The extent of our co-promotion activities and the fee that we will be paid by Wyeth for these activities will be established if, as and when we exercise our option. Wyeth will record all sales of products worldwide (including those sold by us, if any, under a Co-Promotion Agreement). Wyeth may terminate any Co-Promotion Agreement if a top 15 pharmaceutical company acquires control of us. Our potential right to commercialize any product, including our Co-Promotion Option, is not essential to the usefulness of the already delivered products or services (*i.e.*, our development obligations) and our failure to fulfill our co-promotion obligations would not result in a full or partial refund of any payments made by Wyeth to us or reduce the consideration due to us by Wyeth or give Wyeth the right to reject the products or services previously delivered by us.

We are recognizing revenue in connection with the Wyeth Collaboration Agreement under the SAB 104 and will apply the Substantive Milestone Method (see Note 2). In accordance with the EITF 00-21 all of our deliverables under the Wyeth Collaboration

## PROGENICS PHARMACEUTICALS, INC.

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

Agreement, consisting of granting the license for RELISTOR, transfer of supply contracts with third party manufacturers of RELISTOR, transfer of know-how related to RELISTOR development and manufacturing, and completion of development for the subcutaneous and intravenous formulations of RELISTOR in the U.S., represent one unit of accounting since none of those components has standalone value to Wyeth prior to regulatory approval of at least one product; that unit of accounting comprises the development phase, through regulatory approval, for the subcutaneous and intravenous formulations in the U.S.

Within five business days of execution of the Collaboration Agreement, Wyeth made a non-refundable, non-creditable upfront payment of \$60.0 million, for which we deferred revenue at December 31, 2005. Subsequently, we are recognizing revenue related to the upfront license payment over the period during which the performance obligations, noted above, are being performed using the proportionate performance method. We expect that period to extend through 2009. We are recognizing revenue using the proportionate performance method since we can reasonably estimate the level of effort required to complete our performance obligations under the Wyeth Collaboration Agreement and such performance obligations are provided on a best-efforts basis. Full-time equivalents are being used as the measure of performance. Under the proportionate performance method, revenue related to the upfront license payment is recognized in any period as the percent of actual effort expended in that period relative to expected total effort. The total effort expected is based upon the most current budget and development plan which is approved by both us and Wyeth and includes all of the performance obligations under the arrangement. Significant judgment is required in determining the nature and assignment of tasks to be accomplished by each of the parties and the level of effort required for us to complete our performance obligations under the arrangement. The nature and assignment of tasks to be performed by each party involves the preparation, discussion and approval by the parties of a development plan and budget. Since we have no obligation to develop the subcutaneous and intravenous formulations of RELISTOR outside the U.S. or the oral formulation at all and have no significant commercialization obligations for any product, recognition of revenue for the upfront payment is not required during those periods, if they extend beyond the period of our development obligations. If Wyeth terminates the Collaboration in accordance with its terms, we will recognize any unamortized remainder of the upfront payment at the time of the termination.

The amount of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 was based upon several revised approved budgets, although the revisions to those budgets did not materially affect the amount of revenue recognized in those periods. During the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased significantly based upon a revised development budget approved by both us and Wyeth. As a result, the period over which our obligations will extend, and over which the upfront payment will be amortized, was extended from the end of 2008 to the end of 2009. Consequently, the amount of revenue recognized from the upfront payment during the year ended December 31, 2008 declined relative to that in the comparable period of 2007.

Beginning in January 2006, costs for the development of RELISTOR incurred by Wyeth or us are being paid by Wyeth. Wyeth has the right once annually to engage an independent public accounting firm to audit expenses for which we have been reimbursed during the prior three years. If the accounting firm concludes that any such expenses have been understated or overstated, a reconciliation will be made. We are recognizing as research and development revenue from collaborator, amounts received from Wyeth for reimbursement of our development expenses for RELISTOR as incurred under the development plan agreed to between us and Wyeth. In addition to the upfront payment and reimbursement of our development costs, Wyeth has made or will make the following payments to us, provided specific milestones, including clinical, regulatory and sales events, are reached, and taking in to account the modifications made in connection with the Ono transaction discussed in Note 1, above: (i) development and sales milestones and contingent payments, consisting of defined non-refundable, non-creditable payments, totaling \$334.0 million, in respect of clinical and regulatory events and, for each form approved as a commercial product, combined annual worldwide (excluding Japan) net sales, as defined, and (ii) sales royalties during each calendar year during the royalty period, as defined, based on certain percentages of net sales in the U.S. and worldwide (excluding Japan). Upon achievement of defined substantive development milestones by us for the subcutaneous and intravenous formulations, the milestone payments will be recognized as revenue. Recognition of revenue for developmental contingent events related to the oral formulation, which is the responsibility of Wyeth, will be recognized as revenue when Wyeth achieves those events, if they occur subsequent to completion by us of our development obligations, since we would have no further obligations related to those products. Otherwise, if Wyeth achieves any of those events before we have completed our development obligations, recognition of revenue for the Wyeth contingent events will be recognized over the period from receipt of the milestone payment to the completion of our development obligations. All sales milestones will be recognized as revenue when earned.

During the years ended December 31, 2006, 2007 and 2008, we recognized \$18.8 million, \$16.4 million and \$10.2 million, respectively, of revenue from the \$60.0 million upfront payment and \$34.6 million, \$40.1 million and \$24.7 million, respectively, as reimbursement for our out-of-pocket development costs, including our labor costs. In October 2006, we earned a \$5.0 million milestone payment in connection with the start of a phase 3 clinical trial of intravenous RELISTOR for the treatment of POI. In May 2007, April 2008 and July 2008, we earned \$9.0 million, \$15.0 million and \$10.0 million, respectively, in

## PROGENICS PHARMACEUTICALS, INC.

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

milestone payments upon the submission and approval for review of applications for marketing in the U.S. and European Union of the subcutaneous formulation of RELISTOR in patients receiving palliative care, the FDA approval of subcutaneous RELISTOR in the U.S. and the European approval of subcutaneous formulation of RELISTOR, respectively. We considered those milestones to be substantive based on (i) the significant degree of risk, at the inception of the Collaboration, related to the conduct and successful completion of clinical trials and, therefore, of not achieving the milestones, (ii) the amount of the payment received relative to the significant costs incurred since inception of the Wyeth Collaboration Agreement and amount of effort expended to achieve the milestones, and (iii) the passage of 17, 28 and 31 months, respectively, from inception of the Wyeth Collaboration Agreement to the achievement of those milestones. Therefore, we recognized the milestone payments as revenue in the respective periods in which the milestones were earned. As of December 31, 2008, relative to the \$60.0 million upfront license payment received from Wyeth, we have recorded \$14.6 million as deferred revenue – current, which is expected to be recognized as revenue over the period of our development obligations relating to RELISTOR. In addition, at December 31, 2008, we recorded \$1.6 million as deferred revenue - current, related to reimbursements from Wyeth for development costs.

Royalty revenue is recognized upon the sale of related products, 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. If royalties are received when we have remaining performance obligations, they would be attributed to the services being provided under the arrangement and, therefore, recognized as such obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies above.

In addition, during year ended December 31, 2008, we earned royalties of \$665, based on the net sales of subcutaneous RELISTOR, and we recognized \$146 of royalty income. As of December 31, 2008, we have recorded a cumulative total of \$519 as deferred revenue – current, which is expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR. We incurred \$67 of royalty costs and recognized \$15 of royalty expenses during the year ended December 31, 2008. As of December 31, 2008, we recorded a cumulative total of \$52 of deferred royalty costs from the royalty costs incurred during the last three quarters of 2008. The \$52 of deferred royalty costs are expected to be recognized as royalty expense over the period of our development obligations relating to RELISTOR.

The Wyeth Collaboration Agreement extends, unless terminated earlier, on a country-by-country and product-by-product basis, until the last to expire royalty period for any product. We may terminate the Wyeth Collaboration Agreement at any time upon 90 days written notice to Wyeth upon Wyeth's material uncured breach (30 days in the case of breach of a payment obligation). Wyeth may, with or without cause, terminate the Collaboration effective on or after the second anniversary of the first U.S. commercial sale of RELISTOR, by providing us with at least 360 days prior written notice. Wyeth may also terminate the agreement (i) upon 30 days written notice following one or more serious safety or efficacy issues that arise and (ii) upon 90 days written notice of a material uncured breach by us. Upon termination of the Wyeth Collaboration Agreement, the ownership of the license we granted to Wyeth will depend on which party initiates the termination and the reason for the termination.

In October 2008, we entered into an exclusive license agreement with Ono under which we licensed to Ono the rights to subcutaneous RELISTOR in Japan and under that agreement, in November 2008, we received from Ono an upfront payment of \$15.0 million. As of December 31, 2008, relative to the \$15.0 million upfront payment from Ono, we have recorded \$15.0 million as deferred revenue – current, which we expect to recognize as revenue during the first quarter of 2009, upon satisfaction of our performance obligations.

Ono is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Ono is to own the subcutaneous filings and approvals relating to RELISTOR in Japan. We have received a \$15.0 million upfront payment from Ono, and are entitled to receive up to an additional \$20.0 million, payable upon achievement of 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. Supervision of and consultation with respect to Ono's development and commercialization responsibilities will be carried out by joint committees consisting of members from both Ono and us. Ono may request us to perform activities related to its development and commercialization responsibilities beyond our participation in these committees and specified technology transfer-related tasks which will be at its expense, and payable to us for the services it requests, at the time we perform services for them.

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — continued**  
(amounts in thousands, except per share amounts or unless otherwise noted)

**10. Acquisition of Contractual Rights from Licensors**

In 2005, we acquired substantially all of the assets of UR Labs, Inc. (“URL”), comprised in part of an exclusive sublicense agreement to develop and commercialize methylnaltrexone, the active ingredient of RELISTOR, under rights URL licensed from the University of Chicago. We accounted for the acquisition of the rights and responsibilities as an asset purchase. The acquired rights relate to the methylnaltrexone and our research and development activities for methylnaltrexone, for which technological feasibility had not yet been established, for which there was no identified alternative future use, and which had not received regulatory approval for marketing. We continue to have an obligation for payments (including royalties) to the University of Chicago.

**11. Commitments and Contingencies**

**a. Operating Leases**

As of December 31, 2008, we lease office and laboratory space, as follows:

<u>Leased Space</u>	<u>Area (Square Feet)</u>	<u>Termination Date</u>	<u>Other Terms</u>
Sublease 1	91.7	December 30, 2009	
Lease 1	32.6	December 31, 2009	Renewable for two five-year terms
Sublease 2	5.9	June 29, 2012	Four months rent-free beginning April 1, 2006; converts to Lease 2
Lease 2		December 31, 2014	
Lease 3	9.2	June 29, 2012	Three months rent-free beginning August 13, 2007; renewable for two five-year terms; lease incentive of \$276 provided by the landlord
Lease 4	6.5	August 31, 2012	Renewable for two terms co-terminous with Lease 1
Total	<u>145.9</u>		

Such amounts are recognized as rent expense on a straight-line basis over the term of the respective leases, including rent-free periods. 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 August 2010. At the inception of Lease 3, in August 2007, the landlord agreed to pay \$276 of leasehold improvements related to the renovation of that office space. That lease incentive is being amortized as a reduction of rent expense on a straight-line basis over the initial term of the lease.

As of December 31, 2008, future minimum annual payments under all operating lease agreements are as follows:

<u>Years ending December 31,</u>	<u>Minimum Annual Payments</u>
2009	\$ 3,238
2010	504
2011	517
2012	391
2013	194
Thereafter	194
Total	<u>\$ 5,038</u>

## PROGENICS PHARMACEUTICALS, INC.

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

Rental expense totaled approximately \$1,694, \$2,415 and \$2,971 for the years ended December 31, 2006, 2007 and 2008, respectively. For the years ended December 31, 2006 and 2007, we recognized rent expense in excess of amounts paid of \$74 and \$17, respectively, due to the recognition of escalation clauses and lease incentives. For the year ended December 31, 2008, amounts paid exceeded rent expense by \$93, due to the recognition of escalation clauses and lease incentives. Additional facility charges, including utilities, taxes and operating expenses, for the years ended December 31, 2006, 2007 and 2008 were approximately \$2,932, \$2,974 and \$3,533, respectively.

#### **b. Licensing, Service and Supply Agreements of Progenics Pharmaceuticals, Inc.**

Progenics has entered into a variety of intellectual property-based license and service agreements in connection with its product development programs. During 2005, we also entered into a supply agreement for methylnaltrexone. During 2006, we transferred that agreement and the obligation for the manufacture of methylnaltrexone, in bulk and finished form, to Wyeth. In connection with all the agreements discussed below, Progenics has recognized milestone, license and sublicense fees and supply costs, which are included in research and development expenses, totaling approximately \$1,825, \$350 and \$1,529 for the years ended December 31, 2006, 2007 and 2008, respectively. In addition, as of December 31, 2008, remaining payments, including amounts accrued, associated with milestones and defined objectives as well as annual maintenance fees with respect to the agreements referred to below total approximately \$4,325.

##### *i. Columbia University*

For a number of years, we have been party to a license agreement with Columbia University (“Columbia”) under which we obtained rights to technology and materials for a program we have since terminated. As of December 31, 2008, we had paid Columbia a total of \$890,000 under this license agreement, including \$25,000 in royalties. In January 2009, we and Columbia agreed to terminate and amend certain rights granted in this license in exchange for a one-time payment of \$300,000, which was accrued as of December 31, 2008. Under this new arrangement, we retain rights to certain technology for sales of reagents and other purposes, subject to royalties.

##### *ii. Sloan-Kettering Institute for Cancer Research*

We were a party to a license agreement with Sloan-Kettering under which we obtained the worldwide, exclusive rights to specified technology relating to ganglioside conjugate vaccines, including GMK, and its use to treat or prevent cancer. The license was terminated on February 15, 2008.

##### *iii. Aquila Biopharmaceuticals, Inc.*

For a number of years, we were party to a license and supply agreement with Aquila Biopharmaceuticals, Inc., a wholly owned subsidiary of Antigenics Inc., for a program we have since terminated. In November 2008, the agreement was terminated and a portion of the contingent shares issued to Aquila in connection with the agreement have since been cancelled.

##### *iv. Facet Biotech Corporation (formerly, Protein Design Labs, Inc.)*

Protein Design Labs (now Facet Biotech Corporation (“Facet”)) humanized a murine monoclonal antibody developed by us (humanized PRO 140) and granted us related licenses under patents and patent applications, in addition to know-how. In general, these licenses are fully paid after the latest of the tenth anniversary of the first commercial sale of a product developed thereunder, expiration of the last-to-expire patent or the tenth anniversary of the latest filed pending patent application. Pending U.S. and international patent applications and patent-term extensions may extend the period of our license rights when and if they are allowed, issued or granted. We may terminate the license on 60 days prior written notice, and either party may terminate on 30 days prior written notice for an uncured material breach (ten days for payment default). As of December 31, 2008, we have paid Facet’s predecessors \$5.2 million, and if all milestones are achieved, we will be obligated to pay an additional approximately \$2.0 million. We are also required to pay annual maintenance fees of \$150,000 and royalties on sales of products developed under the license.

##### *v. UR Labs, Inc./ University of Chicago*

We have an exclusive sublicense agreement with URL to develop and commercialize methylnaltrexone under rights URL licensed from the University of Chicago. After entering this sublicense, we subsequently acquired substantially all of the assets of

## PROGENICS PHARMACEUTICALS, INC.

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

URL, comprised of its rights and responsibilities under its University of Chicago license, its sublicense with us and related agreements, and at the same time modified some of those obligations to third parties. As a result, our only remaining obligations represent payments to the University of Chicago under the license.

We have also entered into two agreements with the University of Chicago which give us the option to license certain of its intellectual property over defined option periods. As of December 31, 2008, we have paid the University of Chicago \$540,000 and may make payments aggregating \$660,000 over the option periods.

#### **c. Licensing and Collaboration Agreements of PSMA Development Company LLC**

In connection with all the agreements discussed below, PSMA LLC, which became our wholly owned subsidiary on April 20, 2006 (see Note 12) has recognized milestone, license and annual maintenance fees, which are included in research and development expenses of PSMA LLC, totaling approximately \$200, \$600 and \$865 for the years ended December 31, 2006, 2007 and 2008, respectively. In addition, in connection with our acquisition of a former member's interest in PSMA LLC (see Note 12), the former member granted an exclusive license to PSMA LLC, under which PSMA LLC recognized \$25, \$38 and \$28 in license fees for the years ended December 31, 2006, 2007 and 2008, respectively. As of December 31, 2008, remaining payments, including amounts accrued, associated with milestones and defined objectives with respect to the agreements referred to below, as well as with respect to the license granted by the former member to PSMA LLC, total approximately \$78.1 million.

##### *i. Amgen Fremont, Inc. (formerly Abgenix)*

PSMA LLC has a worldwide exclusive licensing agreement with Abgenix (now Amgen Fremont, Inc.) to use its Xenomouse<sup>®</sup> technology for generating fully human antibodies to PSMA LLC's PSMA antigen. PSMA LLC is obligated to make payments under this license upon the occurrence of defined milestones associated with the development and commercialization program for products incorporating an antibody generated utilizing the Xenomouse technology. As of December 31, 2008, PSMA LLC has paid to Abgenix \$850,000 under this agreement. If PSMA LLC achieves certain milestones specified under the agreement, it will be obligated to pay Abgenix up to an additional \$6.25 million. In addition, PSMA LLC is required to pay royalties based upon net sales of antibody products, if any. This agreement may be terminated, after an opportunity to cure, by Abgenix for cause upon 30 days prior written notice. PSMA LLC has the right to terminate this agreement upon 30 days prior written notice. If not terminated early, this agreement continues until the later of the expiration of the Xenomouse technology patents that may result from pending patent applications or seven years from the first commercial sale of the products.

##### *ii. AlphaVax Human Vaccines*

PSMA LLC has a worldwide exclusive license agreement with AlphaVax Human Vaccines ("Alpha Vax") to use its AlphaVax Replicon Vector system to create a therapeutic prostate cancer vaccine incorporating PSMA LLC's proprietary PSMA antigen. PSMA LLC is obligated to make payments under the license upon the occurrence of certain milestones associated with the development and commercialization program for products incorporating AlphaVax's system. As of December 31, 2008, PSMA LLC has paid to AlphaVax \$1.7 million under this agreement. If PSMA LLC achieves certain milestones specified under the agreement, it will be obligated to pay AlphaVax up to an additional \$5.3 million. In addition, PSMA LLC is required to pay annual maintenance fees of \$100,000 until the first commercial sale and royalties based upon net sales of any products developed using AlphaVax' system. This agreement may be terminated, after an opportunity to cure, by AlphaVax under specified circumstances, including PSMA LLC's failure to achieve milestones; the consent of AlphaVax to revisions to the milestones due dates may not, however, be unreasonably withheld. PSMA LLC has the right to terminate the agreement upon 30 days prior written notice. If not terminated early, this agreement continues until the later of the expiration of the patents relating to AlphaVax's system or seven years from the first commercial sale of the products developed using that system. Pending U.S. and international patent applications and patent-term extensions may extend the period of our license rights when and if they are allowed, issued or granted.

##### *iii. Seattle Genetics, Inc.*

PSMA LLC has a collaboration agreement with Seattle Genetics, Inc. ("SGI"), under which SGI has granted PSMA LLC an exclusive worldwide license to its proprietary ADC technology. Under the license, PSMA LLC has the right to use this technology to link chemotherapeutic agents to PSMA LLC's monoclonal antibodies that target prostate specific membrane antigen. The ADC technology is based, in part, on technology licensed by SGI from third parties. PSMA LLC is responsible for research, product development, manufacturing and commercialization of all products under the SGI agreement. PSMA LLC may

## PROGENICS PHARMACEUTICALS, INC.

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

sublicense the ADC technology to a third party to manufacture ADCs for both research and commercial use. Under the agreement, PSMA LLC is obligated to make maintenance payments, additional payments aggregating up to \$14.0 million upon the achievement of certain milestones 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. PSMA LLC may terminate the SGI agreement upon advance written notice to SGI. SGI may terminate the agreement if PSMA LLC fails to cure a breach of an SGI in-license within a specified time period after written notice. In addition, either party may terminate the SGI agreement after written notice upon an uncured breach or in the event of bankruptcy of the other party. As of December 31, 2008, PSMA LLC has paid to SGI approximately \$3.6 million under this agreement, including \$1.0 million in milestone payments.

#### **d. Consulting Agreements**

As part of our research and development efforts, we enter into consulting agreements with external scientific specialists (“Scientists”). 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 Scientists are members of the Progenics’ Scientific Advisory Board (the “SAB Members”), including Stephen P. Goff, Ph.D. and David A. Scheinberg, M.D., Ph.D., both of whom are also members of our Board of Directors. Some Scientists have purchased our Common Stock or received stock options which are subject to vesting provisions. We have recognized expenses with regard to the consulting agreements of the SAB Members totaling approximately \$893, \$1,092 and \$358 for the years ended December 31, 2006, 2007 and 2008, respectively. Those expenses include the fair value of stock options granted during 2006, 2007 and 2008, which were fully vested at grant date, of approximately \$620, \$691 and \$217, respectively. For the year ended December 31, 2007, those expenses include a portion of restricted stock, granted in 2007, that vested in 2007, of approximately \$127. Such amounts of fair value are included in research and development compensation expense for each year presented (see Note 3).

#### **12. PSMA Development Company LLC**

PSMA LLC was formed on June 15, 1999 as a joint venture between us and a former member (each a “Member” and collectively, the “Members”) for the purposes of conducting research, development, manufacturing and marketing of products related to PSMA. On April 20, 2006, we acquired the former member’s 50% membership interest in PSMA LLC, including its economic interests in capital, profits, losses and distributions of PSMA LLC and its voting rights, in exchange for a cash payment of \$13.2 million (the “Acquisition”). We also paid \$259 in transaction costs related to the Acquisition. In connection with the Acquisition, the Licensing Agreement entered into by the Members upon the formation of PSMA LLC, under which the former member had granted a license to PSMA LLC for certain PSMA-related intellectual property, was amended.

Since the acquired intellectual property and license rights relate to research and development projects that, at the acquisition date, had not reached technological feasibility, did not have an identified alternative future use and had not received regulatory approval from the FDA for marketing, at the acquisition date we charged \$13,209 to research and development expense after consideration of the transaction costs and net tangible assets acquired.

#### **13. 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 2006, 2007 and 2008, we matched 100% 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 \$1,135, \$1,538 and \$1,727 to the Amended Plan for the years ended December 31, 2006, 2007 and 2008, respectively. No discretionary contributions were made during those years.

#### **14. Income Taxes**

We account for income taxes using the liability method in accordance with FAS 109. 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.

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — continued**  
(amounts in thousands, except per share amounts or unless otherwise noted)

There is no provision or benefit for federal or state income taxes for the years ended December 31, 2006, 2007 or 2008. We have completed a calculation, under Internal Revenue Code Section 382, the results of which indicate that past ownership changes will limit utilization of net operating loss carry-forwards (“NOL’s”) in the future. Future ownership changes 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 consist of the following:

	December 31,	
	2007	2008
Depreciation and amortization	\$ 5,912	\$ 6,231
R&E tax credit carry-forwards	8,203	9,139
AMT credit carry-forwards	306	306
Net operating loss carry-forwards	73,792	87,672
Deferred revenue	10,632	12,396
Stock compensation	8,155	10,923
Other items	2,713	2,402
	109,713	129,069
Valuation allowance	(109,713)	(129,069)
	\$ —	\$ —

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. The increase in the valuation allowance resulted primarily from the additional net operating loss carry-forwards.

The following is a reconciliation of income taxes computed at the Federal statutory income tax rate to the actual effective income tax provision:

	Year Ended December 31,		
	2006	2007	2008
U.S. Federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of Federal benefit	(5.8)	(5.6)	(5.4)
Research and experimental tax credit	(6.4)	(4.2)	(4.3)
Change in valuation allowance	43.1	40.8	43.3
Other	3.1	3.0	0.4
Income tax provision	0.0%	0.0%	0.0%

As of December 31, 2008, we had available, for tax return purposes, unused NOL’s of approximately \$239.5 million, which will expire in various years from 2018 to 2028, \$17.4 million of which were generated from deductions that, when realized, will reduce taxes payable and will increase 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 its FIN 48 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. Upon adoption of FIN 48 on January 1, 2007 and during the years ended December 31, 2007 and 2008, 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. As of the date of adoption and at December 31, 2008, there were no amounts of unrecognized tax benefits that, if recognized, would affect the effective tax rate and there were no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months from the respective date. As of December 31, 2008, we are subject to federal and state income tax in the United States. 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. Thus, upon adoption of FIN 48 and at December 31, 2008, our open tax years extend back to 1995, with the exception of 1997, during which we reported net income. No amounts of interest or penalties were recognized in our Consolidated Statements of Operations or Consolidated Balance Sheets upon adoption of FIN 48 or as of and for the years ended December 31, 2007 and 2008.

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — continued**  
(amounts in thousands, except per share amounts or unless otherwise noted)

In connection with our adoption of FAS 123(R) on January 1, 2006 (see Note 3), we elected to implement the short cut method of calculating our pool of windfall tax benefits. Accordingly, our pool of windfall tax benefits on January 1, 2006 was zero because it had NOL's since inception and, therefore, had never recognized any net increases in additional paid-in capital in our annual financial statements related to tax benefits from stock-based employee compensation during fiscal periods subsequent to the adoption of FAS 123 but prior to the adoption of FAS 123(R).

Our research and experimental ("R&E") tax credit carry-forwards of approximately \$9.1 million at December 31, 2008 expire in various years from 2009 to 2028. During the year ended December 31, 2008, research and experimental tax credit carry-forwards of approximately \$91 expired.

**15. Net Loss Per Share**

Our basic net loss per share amounts have been computed by dividing net loss by the weighted-average number of common shares outstanding during the period. For the years ended December 31, 2006, 2007 and 2008, we reported a net loss and, therefore, potential common shares were not included since such inclusion would have been anti-dilutive. The calculations of net loss per share, basic and diluted, are as follows:

	Net Loss (Numerator)	Weighted Average Common Shares (Denominator)	Per Share Amount
<b>2006:</b>			
Basic and diluted	\$ (21,618)	25,669	\$ (0.84)
<b>2007:</b>			
Basic and diluted	\$ (43,688)	27,378	\$ (1.60)
<b>2008:</b>			
Basic and diluted	\$ (44,672)	29,654	\$ (1.51)

For the years ended December 31, 2006, 2007 and 2008, potential common shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive include the following:

	Years Ended December 31,					
	2006		2007		2008	
	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price
Options and warrants	4,663	\$ 15.13	4,703	\$17.56	4,854	\$18.01
Restricted stock	312		454		522	
Total	4,975		5,157		5,376	

**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — continued**  
(amounts in thousands, except per share amounts or unless otherwise noted)

**16. Unaudited Quarterly Results**

Summarized quarterly financial data for the years ended December 31, 2007 and 2008 are as follows:

	Quarter Ended March 31, 2007 (unaudited)	Quarter Ended June 30, 2007 (unaudited)	Quarter Ended September 30, 2007 (unaudited)	Quarter Ended December 31, 2007 (unaudited)
Revenue	\$17,637	\$25,457	\$17,018	\$15,534
Net loss	(10,433)	(2,383)	(15,600)	(15,272)
Net loss per share (basic and diluted)	(0.40)	(0.09)	(0.58)	(0.53)
	Quarter Ended March 31, 2008 (unaudited)	Quarter Ended June 30, 2008 (unaudited)	Quarter Ended September 30, 2008 (unaudited)	Quarter Ended December 31, 2008 (unaudited)
Revenue	\$14,762	\$28,584	\$17,497	\$6,828
Net loss	(15,485)	(2,369)	(12,220)	(14,598)
Net loss per share (basic and diluted)	(0.52)	(0.08)	(0.41)	(0.49)

## 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, hereunto duly authorized.

PROGENICS PHARMACEUTICALS, INC.

By: /s/ PAUL J. MADDON, M.D., PH.D.  
Paul J. Maddon, M.D., Ph.D.  
(Duly authorized officer of the  
Registrant and Chief Executive Officer, Chief  
Science Officer and Director)

Date: March 13, 2009

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

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ KURT W. BRINER</u> Kurt W. Briner	Co-Chairman	March 13, 2009
<u>/s/ PAUL J. MADDON, M.D., PH.D.</u> Paul J. Maddon, M.D., Ph.D.	Chief Executive Officer, Chief Science Officer and Director (Principal Executive Officer)	March 13, 2009
<u>/s/ CHARLES A. BAKER</u> Charles A. Baker	Director	March 13, 2009
<u>/s/ PETER J. CROWLEY</u> Peter J. Crowley	Director	March 13, 2009
<u>/s/ MARK F. DALTON</u> Mark F. Dalton	Director	March 13, 2009
<u>/s/ STEPHEN P. GOFF, PH.D.</u> Stephen P. Goff, Ph.D.	Director	March 13, 2009
<u>/s/ DAVID A. SCHEINBERG, M.D., PH.D.</u> David A. Scheinberg, M.D., Ph.D.	Director	March 13, 2009
<u>/s/ NICOLE S. WILLIAMS</u> Nicole S. Williams	Director	March 13, 2009
<u>/s/ ROBERT A. MCKINNEY, CPA</u> Robert A. McKinney, CPA	Chief Financial Officer, Senior Vice President, Finance & Operations and Treasurer (Principal Financial and Accounting Officer)	March 13, 2009

## EXHIBIT INDEX

Exhibit Number *	Description
3.1(14)	Restated Certificate of Incorporation of the Registrant.
3.2(14)	Amended and Restated By-laws of the Registrant.
4.1(1)	Specimen Certificate for Common Stock, \$0.0013 par value per share, of the Registrant.
10.1(1)	Form of Registration Rights Agreement.
10.2(1)	1989 Non-Qualified Stock Option Plan‡
10.3(1)	1993 Stock Option Plan, as amended‡
10.4(1)	1993 Executive Stock Option Plan‡
10.5(3)	Amended and Restated 1996 Stock Incentive Plan‡
10.6(14)	2005 Stock Incentive Plan‡
10.6.1(10)	Form of Non-Qualified Stock Option Award Agreement‡
10.6.2(10)	Form of Restricted Stock Award Agreement‡
10.6.3(16)	Amended 2005 Stock Incentive Plan ‡
10.6.4(18)	Form of Non-Qualified Stock Option Award Agreement ‡
10.6.5(18)	Form of Restricted Stock Award Agreement ‡
10.7(15)	Form of Indemnification Agreement‡
10.8(19)	Employment Agreement, dated December 31, 2007, between the Registrant and Dr. Paul J. Maddon‡
10.9(1)	Letter dated August 25, 1994 between the Registrant and Dr. Robert J. Israel‡
10.10(8)	Amended 1998 Employee Stock Purchase Plan‡
10.11(8)	Amended 1998 Non-qualified Employee Stock Purchase Plan‡
10.15(5)	Amended and Restated Sublease, dated June 6, 2000, between the Registrant and Crompton Corporation.
10.16(2)†	Development and License Agreements, dated April 30, 1999, between Protein Design Labs, Inc. and the Registrant.
10.16.1(11)	Letter Agreement, dated November 24, 2003, relating to the Development and License Agreement between Protein Design Labs, Inc. and the Registrant.
10.18(4)	Director Stock Option Plan‡
10.19(6)†	Exclusive Sublicense Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.19.1(9)	Amendment to Exclusive Sublicense Agreement, dated September 21, 2001, between the Registrant and UR Labs, Inc.
10.20(7)	Research and Development Contract, dated September 26, 2003, between the National Institutes of Health and the Registrant.
10.21(7)	Agreement of Lease, dated September 30, 2003, between Eastview Holdings LLC and the Registrant.
10.22(7)	Letter Agreement, dated October 23, 2003, amending Agreement of Lease between Eastview Holdings LLC and the Registrant.
10.23(11)	Summary of Non-Employee Director Compensation‡
10.24(12) †	License and Co-Development Agreement, dated December 23, 2005, 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.
10.25(12) †	Option and License Agreement, dated May 8, 1985, by and between the University of Chicago and UR Labs, Inc., as amended by the Amendment to Option and License Agreement, dated September 17, 2005, by and between the University of Chicago and UR Labs, Inc., by the 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 by the 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(13)	Membership Interest Purchase Agreement, dated April 20, 2006, between the Registrant Inc. and Cytogen Corporation.
10.27(13) †	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(17)	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 ††	License Agreement, dated as of October 16, 2008, by and among Ono Pharmaceutical Co., Ltd. and the Registrant.

- 10.30 †† 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 †† 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 †† 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.
- 21.1(19) Subsidiaries of the Registrant.
- 23.1 Consent of PricewaterhouseCoopers LLP.
- 31.1 Certification of Paul J. Maddon, M.D., Ph.D., 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 Robert A. McKinney, Chief Financial Officer, Senior Vice President, Finance and Operations and 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 Paul J. Maddon, M.D., Ph.D., 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 Robert A. McKinney, Chief Financial Officer, Senior Vice President, Finance and Operations and 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.

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\* 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 Registration Statement on Form S-1, Commission File No. 333-13627.
- (2) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1999.
- (3) Previously filed in Registration Statement on Form S-8, Commission File No. 333-120508.
- (4) Previously filed in Annual Report on Form 10-K for the year ended December 31, 1999.
- (5) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2000.
- (6) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2002.
- (7) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ending September 30, 2003.
- (8) Previously filed in Registration Statement on Form S-8, Commission File No. 333-143671.
- (9) Previously filed in Current Report on Form 8-K filed on September 20, 2004.
- (10) Previously filed in Current Report on Form 8-K filed on July 8, 2008.
- (11) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2004.
- (12) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2005.
- (13) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ending June 30, 2006.
- (14) Previously filed in Current Report on Form 8-K filed on May 13, 2005.
- (15) Previously filed in Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2007.
- (16) Previously filed in Registration Statement on Form S-8, Commission File No. 333-143670.
- (17) Previously filed in Annual Report on Form 10-K/A for the year ended December 31, 2006.
- (18) Previously filed in Current Report on Form 8-K filed on July 8, 2008.
- (19) Previously filed in Annual Report on Form 10-K for the year ended December 31, 2007.

† Confidential treatment granted as to certain portions omitted and filed separately with the Commission.

†† Confidential treatment requested as to certain portions omitted and filed separately with the Commission.

‡ Management contract or compensatory plan or arrangement.



# Stockholders' Information

## Securities and Related Information

The Company's Common Stock is traded on the Nasdaq National Market under the symbol PGNX. As of April 13, 2009 the Company had approximately 345 stockholders of record.

Below are high and low sales prices for the Company's Common Stock as reported by Nasdaq for the periods indicated:

<b>2007</b>	<b>(\$)</b>	<b>High</b>	<b>Low</b>	<b>2008</b>	<b>(\$)</b>	<b>High</b>	<b>Low</b>
First Quarter		30.31	20.02	First Quarter		19.25	4.33
Second Quarter		27.59	21.14	Second Quarter		17.94	6.66
Third Quarter		26.10	20.55	Third Quarter		17.50	11.88
Fourth Quarter		23.98	17.77	Fourth Quarter		14.10	6.77

## Company Information

For general and financial information about the Company, please contact:

Progenics Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, NY 10591

Phone: 914-789-2800  
Fax: 914-789-2817

E-mail: [Investor.Relations@progenics.com](mailto:Investor.Relations@progenics.com)  
Website: [www.progenics.com](http://www.progenics.com)

## Annual Meeting of Stockholders

The Annual Stockholders Meeting will be held at 10:00 a.m. Eastern Time on Monday, June 8, 2009 at:

Landmark at Eastview  
Rockland Room  
777 Old Saw Mill River Road  
Tarrytown, NY 10591

## Transfer Agent

American Stock Transfer and Trust Company  
40 Wall Street  
New York, New York 10005

## Independent Accountants

PricewaterhouseCoopers LLP  
300 Madison Avenue  
New York, New York 10017

## Legal Counsel

Dewey & LeBoeuf LLP  
1301 Avenue of the Americas  
New York, New York 10019

Each stockholder will receive a notice of internet availability of proxy materials that will contain instructions on how to access the Company's proxy materials online, or request a printed copy or email copy of these materials at no charge.

**Progenics**<sup>®</sup>  
Pharmaceuticals